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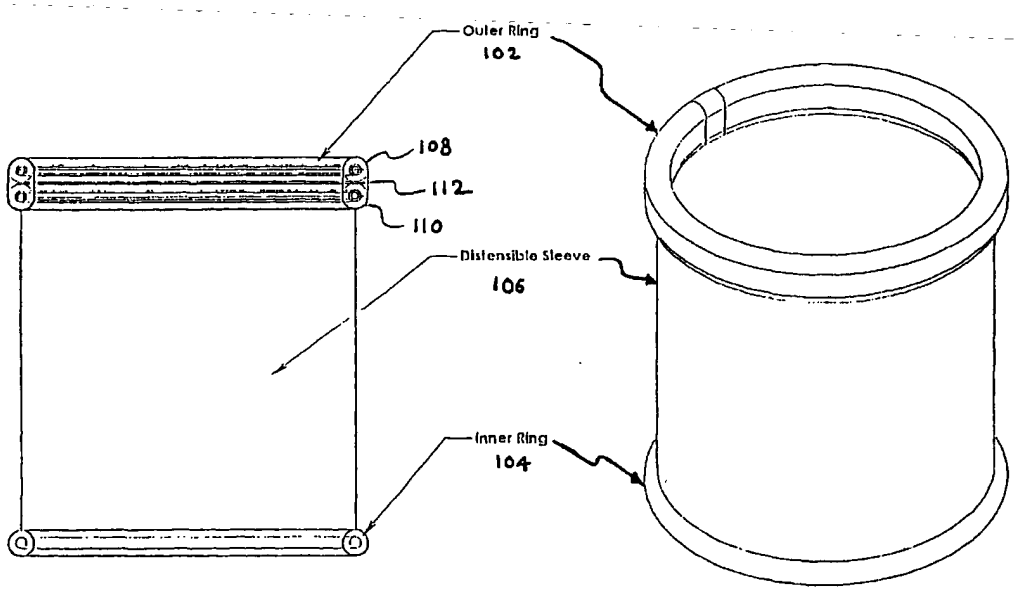

(57) Abstract: An incrementally adjustable wound retractor (199), having a first ring (102) with a diameter greater than the desired diameter of the wound incision. A second ring (104), having an annular axis and a diameter greater than the desired diameter of the wound incision. A flexible sleeve (106), disposed in a generally cylindrical form between the first and the second rings (012, 104), the second ring may be rolled over itself and around the annular axis to provide a sleeve with a radical retraction force sufficient to stretch the incision to the desired diameter.

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WOUND RETRACTOR

This is a non-provisional application claiming the priority of provisional application Serial No. 60/386,159, filed on June 5, 2002, entitled "Omega Wound Retractor," and the priority of provisional application Serial No. 60/415,351, filed on October 2, 2002, entitled "Wound Retractor," both of which are fully incorporated herein by reference.

Background of the Invention

Field of the Invention

This invention generally relates to medical devices and, more specifically, to an improved wound retractor providing ease of incremental retraction and alignment to fit a wide range of incision sizes, including audible and tactile feedback to the user.

Discussion of the Prior Art

Surgery typically involves making an incision large enough to accommodate a surgeon's hand and/or multiple instruments. The incision must be kept clean since it is susceptible to infection if touched by diseased body parts and/or contaminated instruments. As such, wound protectors are available to insure that exposed sides of an incision are covered and protected from contaminants. A common deficiency of wound protectors is their lack of ease of retraction adjustability and stability. U.S. Patent Nos. 5,524,644 and 6,382,211,

both to Crook, attempt to address this deficiency with a wound protector including an outer ring having an oblate cross-section and opposed flat surfaces that allegedly provide retraction adjustability and stability. The oblate design of the outer ring of Crook, however, provides only limited incremental retraction and can be difficult to twist or turn. In addition, the Crook design does not provide for an audible feedback to the user. Accordingly, there is a need in the art for an improved wound retractor that can be easily retracted to fit a wide range of incision sizes. The improved wound retractor preferably provides audible and/or tactile feedback to the user during retraction.

Summary of the Invention

An incrementally adjustable wound retractor for sealing edges of a surgical incision and forming an opening in a patient's body cavity, the wound retractor comprising an inner ring, an outer ring and a flexible sleeve connecting the inner ring and the outer ring. The wound retractor provides a path for a surgeon to insert his hand and/or instruments through the opening formed by the wound retractor. The wound retractor is incrementally adjustable to fit a wide range of incision sizes. The wound retractor is installed or placed in a body cavity such that the inner and outer rings expand around inner and outer edges of the incision. Any portion of the flexible sleeve extending outside the incision can be easily rolled onto the outer ring to tightly seal the sides of the wound. The outer ring is preferably shaped to provide audible and/or tactile feedback to the user. In particular, the outer ring includes surfaces that are easy to grip and turn to allow the user to manually turn the outer ring and roll up the flexible sleeve

with ease. The outer ring may be solid or include a lumen with a rod placed therein to provide audible signal to the user as the outer ring is turned.

These and other features and advantages of the invention will become more apparent with a discussion of preferred embodiments in reference to the associated drawings.

Description of the Drawings

FIG. 1 illustrates a cutaway side view and an isometric view of an incrementally adjustable wound retractor in accordance with an embodiment of the invention;

FIGS. 2a-2d illustrate the retraction of the outer ring of the wound retractor of FIG. 1 to fit a desired incision;

FIG. 3 is a longitudinal cross-section view of the wound retractor of FIG. 1 taken along line A-A;

FIG. 4 illustrates the wound retractor of FIG. 1 installed in an incision;

FIG. 5 is a cross-section view of a hollow tube of an outer ring of a wound retractor in accordance with a second embodiment of the invention;

FIG. 6 is a cross-section view of an inner rod of the outer ring of the wound retractor in accordance with the second embodiment of the invention;

FIG. 7 illustrates a cutaway side view of an incrementally adjustable wound retractor in accordance with the second embodiment of the invention;

FIG. 8 illustrates the retraction and alignment of the outer ring to fit a desired incision size in accordance with the second embodiment of the invention;

FIG. 9 illustrates the wound retractor of FIG. 7 installed in an incision;

FIG. 10 illustrates a longitudinal cross-section view of an outer ring including a wire in accordance with a third embodiment of the invention;

FIGS. 11 and 12 illustrate the rolling of the outer ring to fit a desired incision size in accordance with the third embodiment of the invention;

FIG. 13 is a three-dimensional cross-section view of the wound retractor of FIG. 10;

FIG. 14 is a three-dimensional image of the hollow tube of the outer ring of the wound retractor in accordance with the second embodiment of the invention;

FIG. 15 is a three-dimensional image of the inner rod of the outer ring of the wound retractor in accordance with the second embodiment of the invention;

FIG. 16 is a cross-section view of the hollow tube and inner rod coaxially joined in accordance with the second embodiment of the invention;

FIGS. 17a-17e illustrate cross-section views of additional embodiments of the outer ring of the invention;

FIGS. 18a-18l illustrate cross-section views of additional embodiments of the hollow tube and inner rod of the outer ring of the invention;

FIGS. 19a-19g illustrate cross-section views of additional embodiments of the outer ring of the invention having generally prolate cross-sections;

FIGS. 20a-20g illustrate cross-section views of additional embodiments of the outer ring of the invention having generally prolate cross-sections and including lumens;

FIGS. 21a-21e illustrate cross-section views of additional embodiments of the outer ring of the invention having generally oblate cross-sections;

FIGS. 22a-22e illustrate cross-section views of additional embodiments of the outer ring of the invention having generally oblate cross-sections and including lumens;

FIG. 23a illustrates a cross-section view of another embodiment of the outer ring of the invention having a triangular cross-section;

FIG. 23b illustrates a cross-section view of the outer ring of FIG. 23a further including a lumen;

FIG. 24a illustrates a cross-section view of another embodiment of the outer ring of the invention having a cross-section comprising an odd number of sides such as a pentagon;

FIG. 24b illustrates a cross-section view of the outer ring of FIG. 24a further including a lumen;

FIGS. 25a-25b illustrate different processes of forming the outer ring of the invention;

FIG. 26 illustrates an axial cross-section view of a surgical access device with a slightly modified gel cap and/or abdominal base in accordance with another embodiment of the invention;

FIG. 27 is an axial cross-section view of a surgical access device in accordance with another embodiment of the invention;

FIGS. 28-30 illustrate additional exemplary embodiments of the invention having modifications that could be made to the gel cap and/or the abdominal base so that the surgical access device can be used with the wound retractor;

FIG. 31 illustrates a perspective view of a base of a surgical access device in accordance with another embodiment of the invention;

FIG. 32 is an axial cross-section view of the embodiment illustrated in FIG. 31;

FIGS. 33 and 34 illustrate a base of a surgical access device in accordance with another embodiment of the invention having at least one toggle or latch adapted to fit a corresponding cap ring; and

FIGS. 35 and 36 illustrate a base of a surgical access device in accordance with another embodiment of the invention having a raised wall on an inner diameter and adapted to fit a corresponding cap ring.

Description of Preferred Embodiments and Best Mode of the Invention

FIG. 1 illustrates a wound retractor 100 in accordance with a first embodiment of the invention. The wound retractor 100 comprises a double-tube outer ring 102, an inner ring 104, and a distensible sleeve 106 connecting the outer ring 102 and the inner ring 104. The sleeve 106 may be attached to the outer ring 102 and the inner ring 104 by heat seal or adhesive. The outer ring 102 and the inner ring 104 are preferably made of a material of sufficient hardness to retain their shape after twisting and rolling of the rings. That is, the material must be compliant enough to allow the outer ring 102 to be turned around its annular axis as further described below and illustrated in FIGS. 2a-2d. The shape of the outer ring 102 affects both its ability to grip and to provide stability during and after adjustment. The sleeve 106 is preferably made of a material that is flexible and impermeable to fluids and bacteria. The double-tube outer ring 102 preferably comprises a first circular tube 108 and a second circular

tube 110 joined together by a small web 112. Each of the circular tubes 108 and 110 may be solid or include a lumen.

FIGS. 2a-2d illustrate the retraction and adjustment of the outer ring 102 to fit an incision. In accordance with the invention, the wound retractor 100 is axially adjustable in increments. In particular, the upper end of the sleeve 106 can be wrapped around the outer ring 102 so as to tightly seal the sides or edges of the incision. The unique shape of the outer ring 102 provides for an easy snap action when rolled about itself. The outer ring 102 also provides for incremental shortening of the sleeve 106 and for stability after installation. FIG. 3 illustrates a longitudinal cross-section view of the wound retractor 100 taken along line A-A.

FIG. 4 illustrates a process of installing the wound retractor 100 in a wound opening 400. An incision in the shape of a slit is first made in a patient's body, e.g., the abdominal wall. The inner ring 104 and the sleeve 106 are then manually inserted into body cavity 402 through the incision with the outer ring 102 remaining external to the body cavity 402. Once the inner ring 104 is within the body cavity 402, it expands around the inner surface of the incision so as to be generally parallel to the abdominal wall. The sleeve 106 provides a channel from the outside to the inside of the body cavity 402. The outer ring 102 initially rests above the abdominal wall around the wound opening 400. Since the upper end of the sleeve 106 is connected to the outer ring 102, the sleeve 106 can be drawn upwards and radially outward or inward, thereby drawing the inner ring 104 tightly against the inner surface of the abdominal wall. Moreover, the intermediate portion of the sleeve 106 is drawn tightly against the sides and edges of the wound opening 400, thereby retracting the adjacent tissue and

producing a tightly sealed opening in the body cavity 402. That is, the sleeve 106 contacts the entire wound surface and protectively covers the same and seals it from contamination and infection. Depending on the size and depth of the incision, the user can roll up the sleeve 106 by gripping the double-tube outer ring 102 and turning it in a direction 200 as illustrated in FIGS. 2a-2c until the sleeve 106 abuts the outer edge of the wound opening 400. It should be appreciated that the outer ring 102 can be turned around its annular axis in either an outward or inward direction to roll the sleeve 106.

The outer ring 102 has a unique and novel double-tube configuration wherein through simple manipulation of forcing a first tube in a first direction and a second tube in a second direction, the positions of the first and second tubes can be inverted resulting in fast and easy turning of the tubes as illustrated in FIGS. 2a-2d. In one embodiment of the invention, the outer ring 102 is rotated by pushing the bottom tube or second circular tube 110 inward while pulling the top tube or first circular tube 108 outward (see FIG. 2a). The combination of the above steps results in inversion of the first and second circular tubes as illustrated in FIG. 2d. That is, the outer ring 102 can be rotated in 180^0 turns thereby retracting the sleeve 106. The above process can be repeated until a desired compression or wound opening is achieved.

An advantage of the invention is it provides for an easier, faster and higher retraction rate than that known in the prior art, thereby resulting in less traumatic effects to the patient. Another advantage of the invention is it provides tactile gripping and incremental rolling of the sleeve about the outer ring. In the above description, the first and second tubes of the outer ring are in a vertical position

but it should be appreciated that the first and second tubes may be in different positions relative to one another such as a horizontal position.

In another embodiment of the invention, a small wire 302 such as a stainless steel wire is placed inside a lumen of the double-tube outer ring 102 (see FIGS. 3 and 10-13) so as to provide an audible signal as the outer ring 102 is turned. That is, as the double-tube outer ring 102 is turned, the wire 302 deflects against the tubing wall so as to provide an audible sound feedback to the user. Another feature of the wire 302 is it provides retraction stability to the wound retractor 100.

After surgery, the wound retractor 100 may be retrieved by grabbing the inner ring 104 and the sleeve 106 and pulling them through the wound opening 400. The use of the sleeve 106 and the ease of retracting the outer ring 102 provide higher compression between the inner and outer rings. As a result, the wound retractor 100 of the invention provides incremental adjustability to fit a wide range of incision sizes and isolates and protects the wound from bacterial infection as the diseased body parts and contaminated instruments are passed through the wound.

FIGS. 5-9 and 14-16 illustrate a wound retractor 500 having a roller design in accordance with another embodiment of the invention. The wound retractor 500 comprises an outer ring 502, an inner ring 504, and a distensible sleeve 506 connecting the outer ring 502 and the inner ring 504. The sleeve 506 can be attached to the outer ring 502 and the inner ring 504 by heat seal or adhesive. The outer ring 502 includes a hollow tube or lumen 508 that has a fan-like shape cross-section as illustrated in FIG. 5. The outer ring 502 further comprises an

inner rod 510 that has a similar fan-like geometry on its outer surface as illustrated in FIG. 6. The hollow tube 508 and the inner rod 510 are coaxially joined to form the outer ring 502 of the wound retractor 500.

The fan-like geometry of the outer ring 502 serves as an incremental rotating mechanism. In particular, when the hollow tube 508 is manually rolled out of its coaxial alignment with respect to the inner rod 510, the hollow tube 508 will index itself until it matches the next alignment point of the inner rod 510 as illustrated in FIG. 8. When the hollow tube 508 and the inner rod 510 are coaxially aligned, they lock in place preventing further indexing until the steps of retracting are repeated. It is appreciated that each of the hollow tube 508 and the inner rod 510 has at least one alignment point providing indexing and incremental rotation of the outer ring 502. That is, the outer ring 502 can incrementally retract in steps based on the number of alignment points or indexes on the fan.

FIG. 9 illustrates a process of installing the wound retractor 500 in a wound opening 900. An incision in the shape of a slit is first made in a patient's body, e.g., the abdominal wall. The inner ring 504 and the sleeve 506 are then manually inserted and positioned underneath and along the edges of body cavity wall 512, and the outer ring 502 is pulled through the wound opening 900 so as to be placed outside the body cavity wall 512. Retraction of the sleeve 506 can then be achieved by rolling the outer ring 502 over the sleeve 506 in a direction 700 as shown in FIG. 7 until a desired compression or wound opening is achieved. Incremental retraction is achieved by manually rolling the hollow tube 508 out of its coaxial alignment with the inner rod 510, i.e., the hollow tube 508

can be rolled and indexed to match the next alignment point between the hollow tube 508 and the inner rod 510.

When the hollow tube 508 and the inner rod 510 are coaxially aligned, they lock in place preventing further indexing until the outer ring 502 is rolled out of its alignment again. This process is repeated until a desired retraction is achieved. Once surgery is complete, the wound retractor 500 can be retrieved by grabbing the inner ring 504 and the sleeve 506 and pulling them through the wound opening 900.

It is appreciated that the outer ring can be designed in various shapes and sizes to achieve various retraction rates and/or to conform with different body surfaces as illustrated in FIGS. 17a-17e. For example, the outer ring may comprise a single or multiple tubes of different shapes and sizes. The single or multiple tubes may be solid or include lumens of different shapes and sizes.

Similarly, the wound retractor having the roller design could be of various geometries. As illustrated in FIGS. 18a-18l, hollow tubes 508a-508l and inner rods 510a-510l, respectively, of the outer ring may have different shapes and sizes and may contain multiple locking mechanisms. For example, the inner rods 510b-510e and 510l have solid rectangular cross-sections. In comparison, the inner rods 510f-510k have hollow circular cross-sections. The hollow tubes and inner rods may be made of the same or different materials (e.g., soft and/or hard). For example, the inner rods may be rigid such as a wire or piece of metal, or they may be flexible such as an extension spring. The lumens of the hollow tubes 508a-508l may have cross-sections of different geometries such as fan-like geometry, circular, oval, circular with lumps, triangular, rectangular, any

geometric shape with multiple sides, etc. Advantages of the above embodiments of the invention include improved retraction adjustability and stability.

FIGS. 19a-19g illustrate cross-section views of additional embodiments of the outer ring of the invention having generally prolate cross-sections. That is, the longer axis of the cross-section of the outer ring is generally parallel to axis E-E as illustrated in FIG. 19a. The outer ring can be turned around the axis E-E in either an outward or inward direction 800 to roll up the sleeve (not shown). The outer rings of FIGS. 19a-19g provide tactile gripping and incremental rolling of the sleeve about the rings. FIG. 19b illustrates an outer ring 190 having two straight chordal surfaces 190a and 190b that are generally parallel to the axis E-E. FIG. 19c illustrates an outer ring having two straight chordal surfaces and two curved chordal surfaces. FIGS. 19d-19g illustrate outer rings having at least two curved chordal surfaces.

FIGS. 20a-20g illustrate cross-section views of the outer rings of FIGS. 19a-19g, respectively, further including at least one lumen in each ring. The lumen may house an inner rod (not shown) that deflects against the lumen wall providing an audible feedback to the user. The lumen and inner rod may be of different geometries and sizes.

FIGS. 21a-21e illustrate cross-section views of additional embodiments of the outer ring of the invention having generally oblate cross-sections. That is, the longer axis of the cross-section of the outer ring is generally perpendicular to axis G-G as illustrated in FIG. 21a. The outer ring can be turned around the axis G-G in either an outward or inward direction 900 to roll up the sleeve (not shown). The outer rings of FIGS. 21a-21e provide tactile gripping and incremental rolling

of the sleeve about the rings. FIGS. 21b-21e illustrate outer rings having at least two curved chordal surfaces.

FIGS. 22a-22e illustrate cross-section views of the outer rings of FIGS. 21a-21e, respectively, further including at least one lumen in each ring. The lumen may house an inner rod (not shown) that deflects against the lumen wall providing an audible feedback to the user. The lumen and inner rod may be of different geometries and sizes.

FIG. 23a illustrates a cross-section view of another embodiment of the outer ring of the invention having a triangular cross-section, and FIG. 23b illustrates a cross-section view of the outer ring of FIG. 23a further including a lumen. In another embodiment of the invention, FIG. 24a illustrates a cross-section view of the outer ring of the invention having an odd number of sides such as a pentagon, and FIG. 24b illustrates a cross-section view of the outer ring of FIG. 24a further including a lumen. These outer rings provide tactile gripping and incremental rolling of the sleeve about the rings. The lumens of the outer rings in FIGS. 23b and 24b may be of different shapes and sizes to house inner rods (not shown) having different shapes and sizes. It is appreciated that the outer ring can be designed in various shapes and sizes to achieve various retraction rates and/or to conform with different body shapes.

FIGS. 25a-25b illustrate different processes of forming the outer ring of the invention. The outer ring, which may be solid or include a lumen, may be molded as a circular ring as shown in FIG. 25a, or the outer ring may be formed by joining a single or multiple extruded tubes into a circular ring as shown in FIG. 25b.

In another embodiment of the invention, access into and out of a patient's body is achieved by a hand assisted laparoscopic (HAL) procedure using a surgical access device such as the Gelport™ device as described in applicant's international application PCT/US01/29682, filed on September 21, 2001, entitled "Surgical Access Apparatus and Method," which is incorporated herein by reference, while retraction is provided by the wound retractor of the present invention. The purpose of this embodiment is to combine the features and advantages of both the wound retractor of the present invention and the surgical access device as described in the PCT application. As explained in the PCT application, the current surgical access device uses a polyisoprene sheath that is wrapped distally around an O-ring, and once placed into a wound incision, the sheath is then stretched over extended tabs onto an abdominal base. The sheath of the surgical access device requires stretching and often times requires multiple attempts to secure it to the abdominal base. A novelty of this embodiment is to modify the cap and/or the abdominal base of the surgical access device so that it will accept the wound retractor of the present invention to replace the polyisoprene sheath and to maintain an airtight seal. The use of the wound retractor would simplify the HAL procedure and would not require stretching.

Referring to FIG. 26, there is shown a surgical access device 1000 with slight or moderate modifications to a gel cap 1010 and to an abdominal base 1020. The gel cap 1010 further includes a gel pad 1030 and a circumferential cap ring 1040, which can be inserted and molded to the pad 1030. The resulting gel cap 1010 forms a seal with the base 1020, thereby defining a working

channel through the pad 1030, the cap ring 1040, the base 1020, and the sleeve 106 of the wound retractor. In this manner, the working channel includes a single valve formed by the gel pad 1030 which provides both a zero seal and an instrument seal for a wide range of instrument diameters. Referring to FIG. 27, the cross-section view of gel cap 1010a illustrates an annular void 1042a that is formed on the inner circumference of cap ring 1040a. This void is of particular advantage in forming a sealing relationship with base 1020a. FIGS. 28-30 illustrate additional exemplary embodiments of the invention having modifications that could be made to the gel cap and/or the abdominal base so that the surgical access device can be used with the wound retractor.

FIG. 31 illustrates a perspective view of a base 1020e in accordance with another embodiment of the invention. FIG. 32 is an axial cross-section view of the embodiment illustrated in FIG. 31. From these views, it will be noted that the base 1020e can be provided with a smooth generally cylindrical inner surface 1022e which extends proximally to a rounded end surface 1024e and outwardly from the end surface 1024e along an annular lip 1026e, which is sized and configured to fit into an annular void formed on the inner circumference of a corresponding cap ring. Proximally of the inner surface 1022e, the base 1020e can also include a rounded end surface 1028e along its inner diameter for securing the outer ring of the wound retractor once the sleeve has been shortened.

In another embodiment of the invention, FIGS. 33 and 34 illustrate a base 1020f having a smooth generally cylindrical inner surface 1022f, a rounded end surface 1024f, an annular lip 1026f, and an end surface 1028f having at least one

toggle or latch 1029f sized and configured to fit a corresponding cap ring. In this embodiment, the toggle or latch 1029f operates to change the inner diameter of the cap ring to create a seal or release the cap ring from the base. In yet another embodiment of the invention, FIGS. 35 and 36 illustrate a base 1020g having a smooth generally cylindrical inner surface 1022g, a rounded end surface 1024g, an annular lip 1026g, and an end surface 1028g having a raised wall sized and configured to fit a corresponding cap ring.

An advantage associated with the modified surgical access device is it enables a surgeon to quickly retract and protectively line an abdominal wall incision while being able to easily accommodate variations from patient to patient in the thickness of the abdominal wall. In addition, the device effectively seals around the interior and exterior of the incision, and allows a sealing cap to be attached to seal the abdominal cavity and to enable a laparoscopic procedure to be performed.

Many alterations and modifications may be made by those having ordinary skill in the art without departing from the spirit and scope of the invention. For these reasons, the above description should not be construed as limiting the invention, but should be interpreted as merely exemplary of preferred embodiments.

CLAIMS

1. An adjustable wound retractor adapted to dilate a surgical wound incision to a desired diameter, comprising:

a first ring having a diameter greater than the desired diameter of the wound incision and being adapted for disposition interiorly of the wound incision;

a second ring having an annular axis and a diameter greater than the desired diameter of the wound incision and being adapted for disposition exteriorly of the wound incision; and

a flexible sleeve disposed in a generally cylindrical form between the first ring and the second ring,

wherein the second ring may be rolled over itself and around the annular axis to provide the sleeve with a radial retraction force sufficient to stretch the incision to the desired diameter.

2. The wound retractor of Claim 1, wherein the retractor is incrementally adjustable to fit a wide range of incision sizes.

3. The wound retractor of Claim 1, wherein the second ring has elastomeric properties enabling it to roll over itself to provide a desired retraction force.

4. The wound retractor of Claim 1, wherein any portion of the flexible sleeve extending outside the wound incision can be wrapped around the second ring to tightly seal the sides of the wound incision.

5. The wound retractor of Claim 1, wherein the second ring is shaped to provide at least one of audible and tactile feedback to a user.

6. The wound retractor of Claim 5, wherein the second ring includes surfaces that are easy to grip and turn allowing the user to roll up the flexible sleeve with ease.

7. The wound retractor of Claim 1, wherein the second ring includes a lumen having tubing wall.

8. The wound retractor of Claim 7, further comprising a rod placed inside the lumen to deflect against the tubing wall to provide an audible signal to a user as the second ring is rolled or turned over itself.

9. The wound retractor of Claim 1, wherein the sleeve is made of a material that is flexible and impermeable to fluids and bacteria.

10. The wound retractor of Claim 1, wherein the second ring comprises a double-tube joined by a web.

11. The wound retractor of Claim 10, wherein each of the tubes of the double-tube is circular.

12. The wound retractor of Claim 11, wherein each of the tubes of the double-tube is solid or includes a lumen.

13. The wound retractor of Claim 10, wherein the shape of the double-tube provides for an easy snap-action when rolled about the annular axis.

14. The wound retractor of Claim 8, wherein the rod is a stainless steel wire.

15. The wound retractor of Claim 8, wherein the rod further provides retraction stability to the wound retractor.

16. The wound retractor of Claim 7, further comprising a unidirectional mechanism for retaining the second ring at one of a plurality of positions in order to provide a desired radial retraction force associated with that position.

17. The wound retractor of Claim 16, wherein the unidirectional mechanism includes a one-way roller.

18. The wound retractor of Claim 8, wherein the lumen has a fan-like shape cross-section.

19. The wound retractor of Claim 18, wherein the rod has a fan-like cross-section and is coaxially placed inside the lumen to serve as an incremental rotating mechanism of the wound retractor.

20. The wound retractor of Claim 8, wherein each of the tubing wall and the rod includes a plurality of alignment points that operate to index and match each other as the second ring is rolled out of and into alignment with respect to the rod.

21. The wound retractor of Claim 8, wherein each of the tubing wall and the rod includes at least one alignment point providing indexing and incremental rotation of the second ring.

22. The wound retractor of Claim 7, wherein the lumen of the second ring has a cross-section including circular, oval, circular with at least one lump, rectangular, triangular, and any geometric shape with multiple sides.

23. The wound retractor of Claim 8, wherein the rod has a cross-section including solid rectangular, hollow rectangular, solid circular, hollow circular, and any solid or hollow geometric shape.

24. The wound retractor of Claim 1, wherein the second ring has a generally prolate cross-section.

25. The wound retractor of Claim 1, wherein the second ring can be rolled in either an outward or inward direction to roll up the sleeve.

26. The wound retractor of Claim 24, wherein the second ring comprises two generally straight chordal surfaces parallel to the annular axis.

27. The wound retractor of Claim 26, wherein the second ring further comprises two opposing curved chordal surfaces.

28. The wound retractor of Claim 24, wherein the second ring comprises at least two curved chordal surfaces.

29. The wound retractor of Claim 24, wherein the second ring includes at least one lumen having tubing wall.

30. The wound retractor of Claim 29, further comprising a rod placed inside the lumen to deflect against the tubing wall to provide an audible signal to a user as the second ring is rolled or turned over itself.

31. The wound retractor of Claim 29, wherein the lumen of the second ring has a cross-section including circular, oval, circular with at least one lump, rectangular, triangular, and any geometric shape with multiple sides.

32. The wound retractor of Claim 30, wherein the rod has a cross-section including solid rectangular, hollow rectangular, solid circular, hollow circular, and any solid or hollow geometric shape.

33. The wound retractor of Claim 1, wherein the second ring has a generally oblate cross-section.

34. The wound retractor of Claim 33, wherein the second ring comprises at least two curved chordal surfaces.

35. The wound retractor of Claim 33, wherein the second ring includes at least one lumen having tubing wall.

36. The wound retractor of Claim 35, further comprising a rod placed inside the lumen to deflect against the tubing wall to provide an audible signal to a user as the second ring is rolled or turned over itself.

37. The wound retractor of Claim 35, wherein the lumen of the second ring has a cross-section including circular, oval, circular with at least one lump, rectangular, triangular, and any geometric shape with multiple sides.

38. The wound retractor of Claim 36, wherein the rod has a cross-section including solid rectangular, hollow rectangular, solid circular, hollow circular, and any solid or hollow geometric shape.

39. A surgical access device facilitating a sealing relationship with an instrument extending through the device and into an incision, the access device comprising:

a first ring being adapted for disposition interiorly of the incision;

a second ring having an annular axis and being adapted for disposition exteriorly of the incision;

a flexible sleeve connecting the first ring and the second ring and having properties to roll over itself and around the annular axis to shorten the sleeve in predetermined increments; and

a valve structure disposed relative to the incision to securely receive the second ring.

40. The surgical access device of Claim 39, wherein the rolling properties of the second ring provide the sleeve with a radial retraction force sufficient to stretch the incision to a desired diameter.

41. The surgical access device of Claim 39, wherein the valve structure comprises a gel cap and an abdominal base.

42. The surgical access device of Claim 41, wherein the gel cap further comprises a gel pad and a circumferential cap ring.

43. The surgical access device of Claim 42, wherein the cap ring has an annular void on an inner circumference to form a sealing relationship with the abdominal base.

44. The surgical access device of Claim 41, wherein the abdominal base comprises a rounded end surface along its inner diameter to secure the second ring.

45. The surgical access device of Claim 41, wherein the abdominal base comprises a plurality of toggles along its inner diameter to create a seal with the cap or to release the base from the cap.

46. The surgical access device of Claim 41, wherein the abdominal base comprises a plurality of latches along its inner diameter to create a seal with the cap or to release the base from the cap.

47. The surgical access device of Claim 41, wherein the abdominal base comprises a mating means along its inner diameter to create a seal with the cap or to release the base from the cap.

48. The surgical access device of Claim 41, wherein the abdominal base comprises a raised wall along its inner diameter to fit a corresponding cap ring.

49. The surgical access device of Claim 39, wherein the valve structure forms a pad adapted to be disposed over the incision and forms a seal around the incision, the pad includes a gel material having portions defining an access channel through the pad and extending into communication with the incision.

50. The surgical access device of Claim 39, wherein the instrument comprises an arm of a surgeon.

51. A method for operating an adjustable wound retractor, comprising:

providing a flexible sleeve having a first end attached to a first ring and a second end attached to a second ring, said second ring having properties to roll over itself and around an annular axis to shorten the sleeve in predetermined increments;

inserting the first ring and the sleeve into a patient's body cavity so as to provide a channel from the outside to the inside of the patient's body;

drawing the second end of the sleeve upwards and radially outward or inward thereby drawing the first ring tightly against the inner surface of the body

cavity, and thereby retracting the adjacent tissue and producing a tightly sealed opening in the body cavity; and

rolling the sleeve by gripping the second ring and turning it around the annular axis in either an outward or inward direction until the sleeve abuts the outer edge of the wound incision.

52. The method of Claim 51, further comprising the step of grabbing the first ring and the sleeve and pulling them through the wound opening after surgery.

53. The wound retractor of Claim 1, wherein the second ring is formed from at least two generally circular tubes providing different annular lock points around the annular axis.

54. The wound retractor of Claim 53, wherein each of the tubes is solid or includes a lumen having tubing wall.

55. The wound retractor of Claim 54, further comprising a rod placed inside at least one of the lumen of the tubes to deflect against the tubing wall to provide an audible signal to a user as the second ring is rotated.

56. The wound retractor of Claim 53, wherein the number of tubes forming the second ring determines the number of lock points around the annular axis.

5

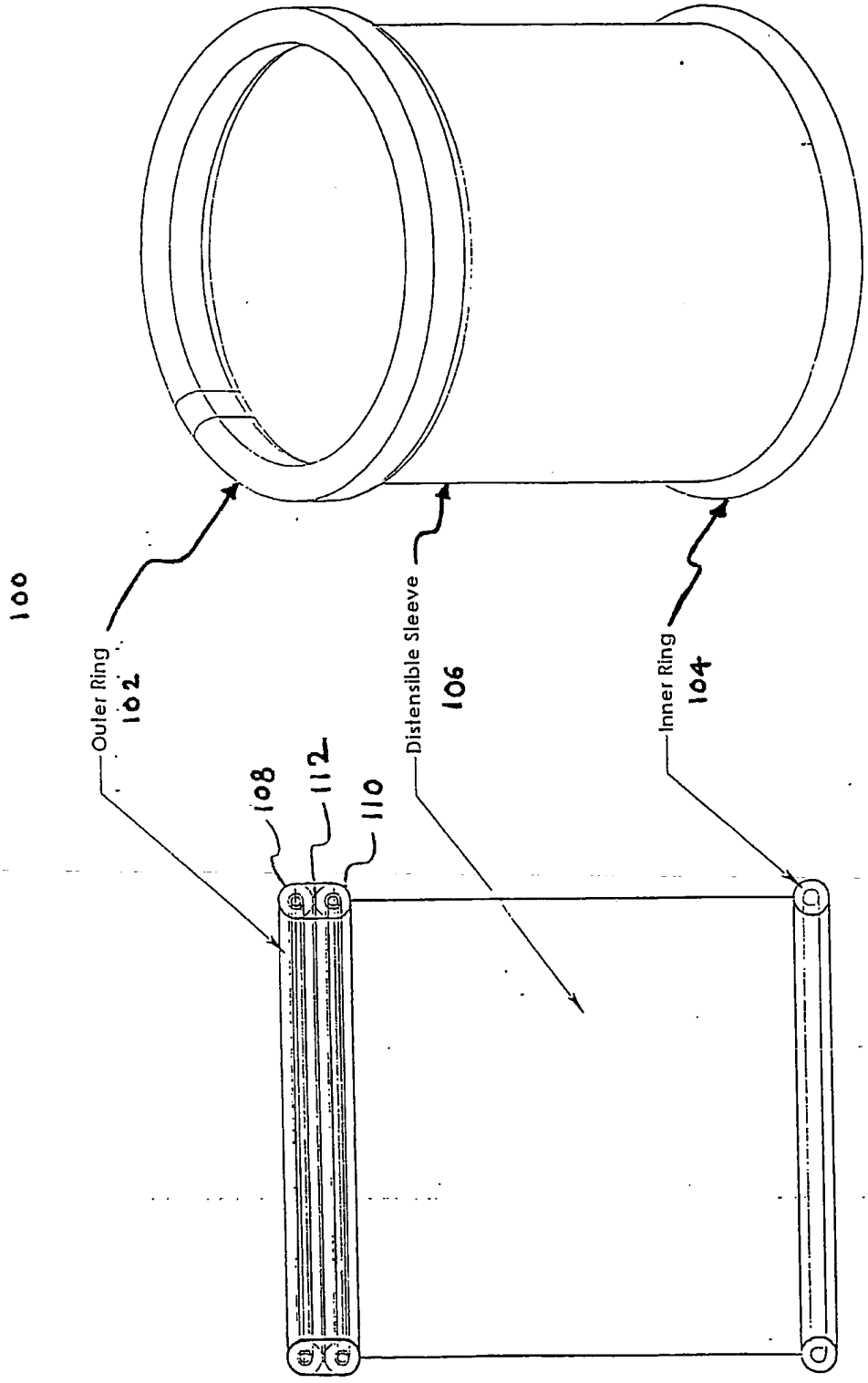

100
Outer Ring
102
Distensible Sleeve
106
Inner Ring
104
108
112
110

FIGURE 1

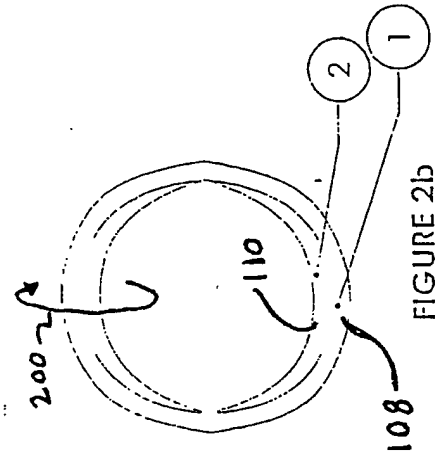


FIGURE 2b

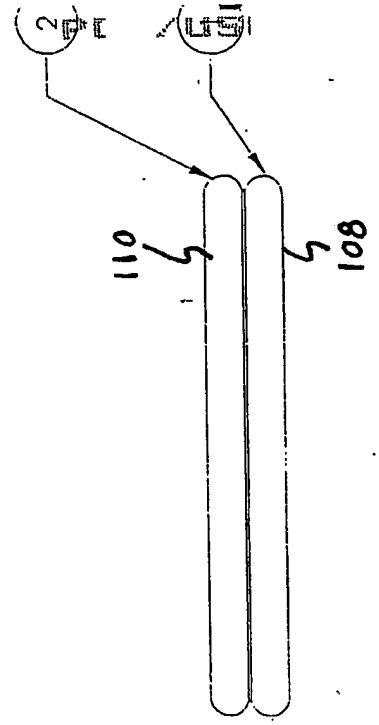


FIGURE 2d

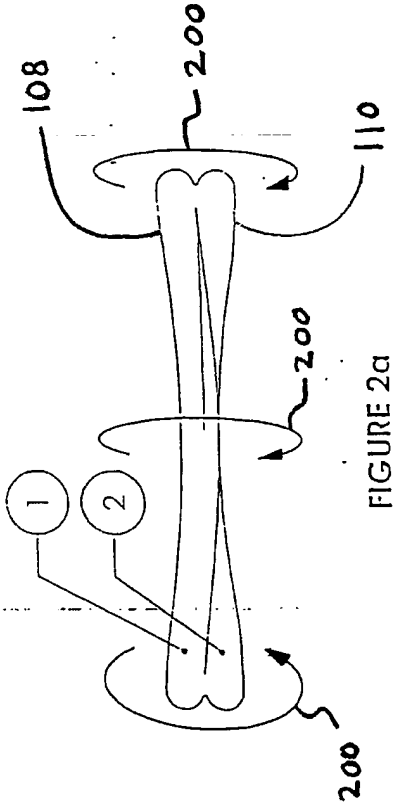


FIGURE 2a

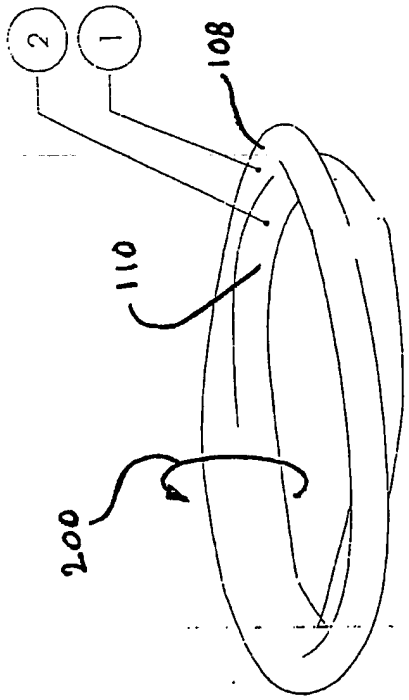


FIGURE 2c

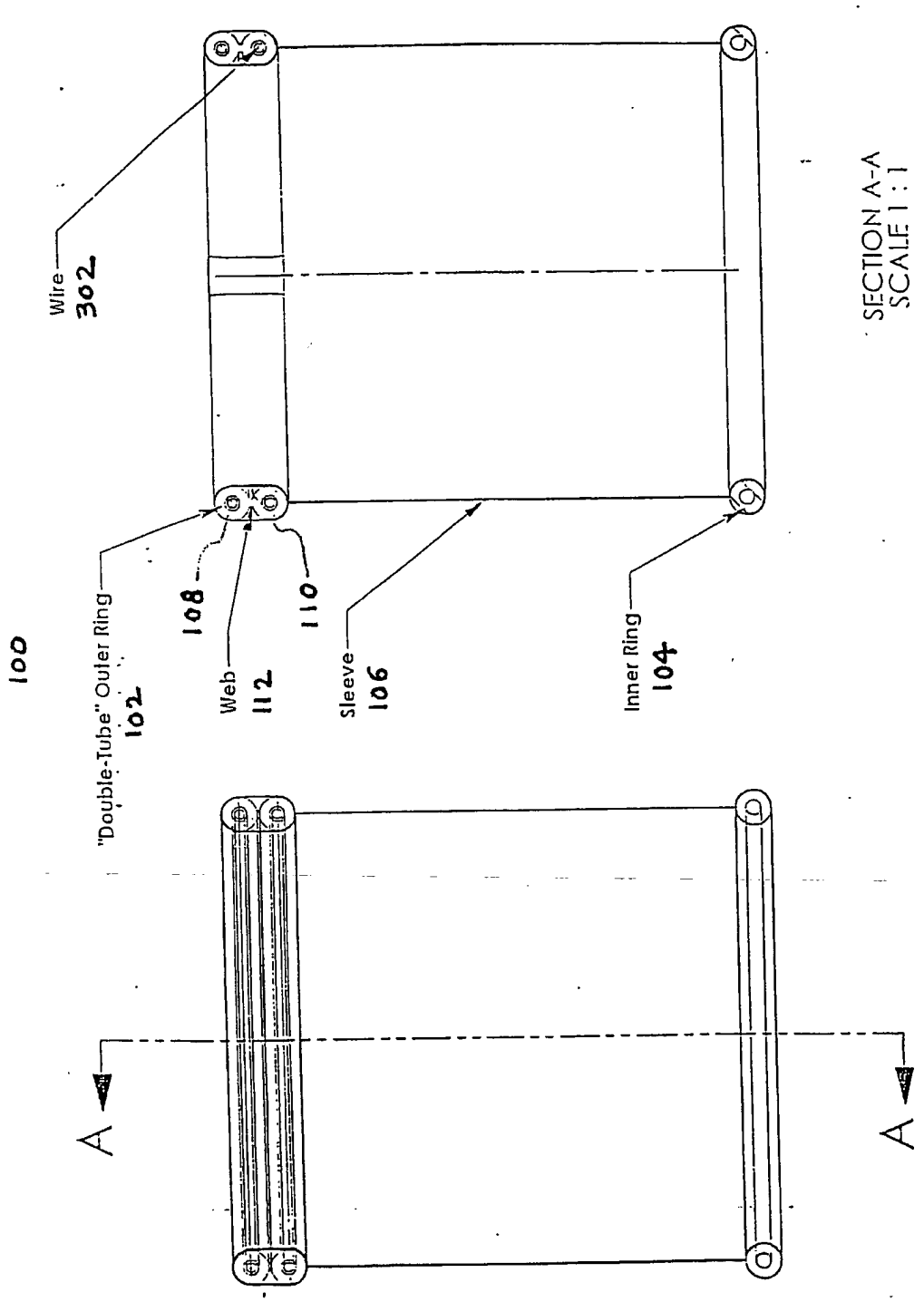

100
Wire
302
"Double-Tube" Outer Ring
102
108
Web
112
110
Sleeve
106
Inner Ring
104
A
A
SECTION A-A
SCALE 1 : 1

FIGURE 3

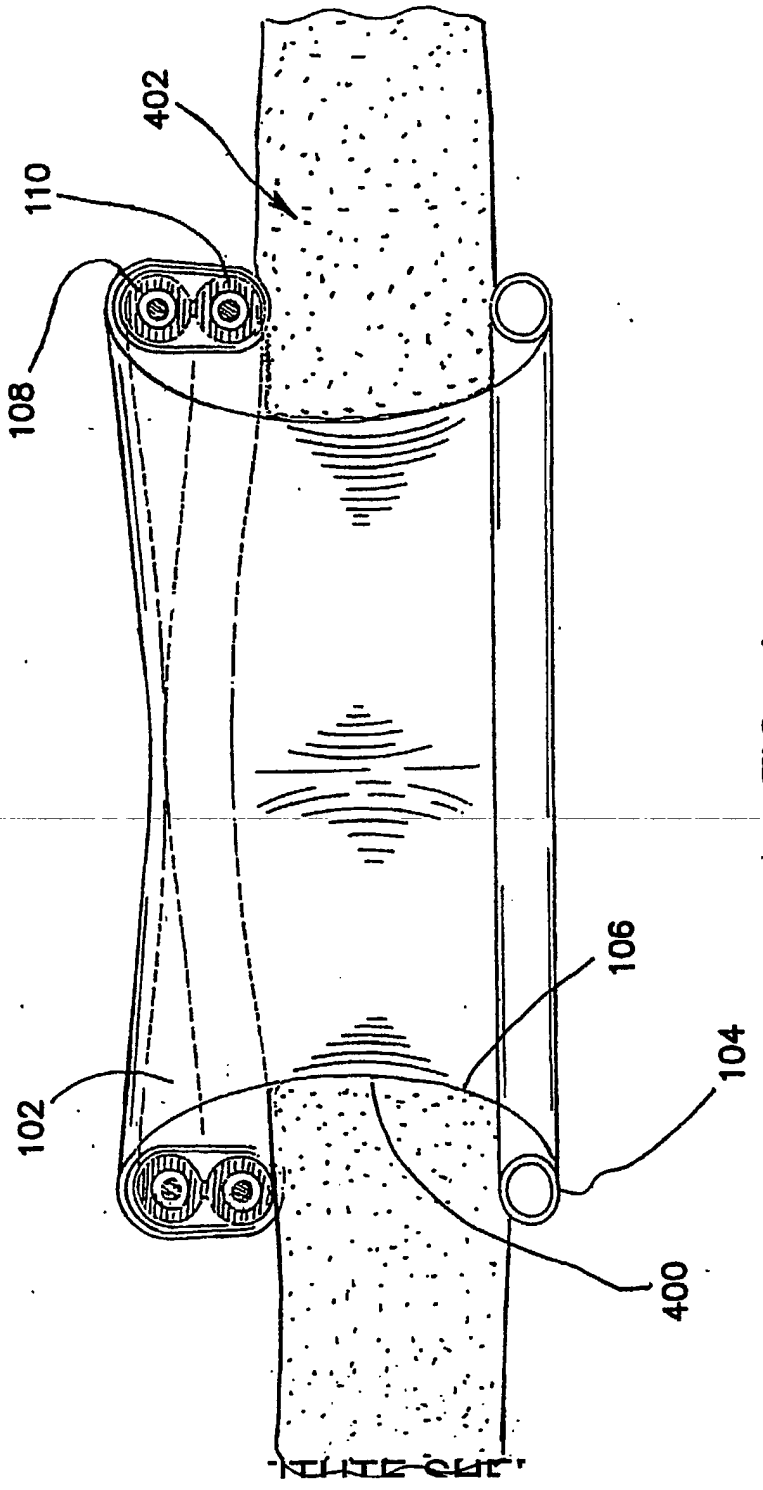


FIG. 4

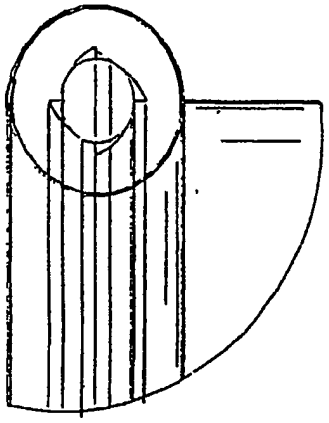


FIG. 7

FIG. 6

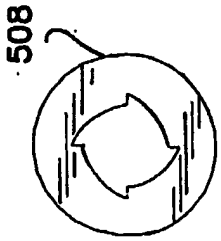
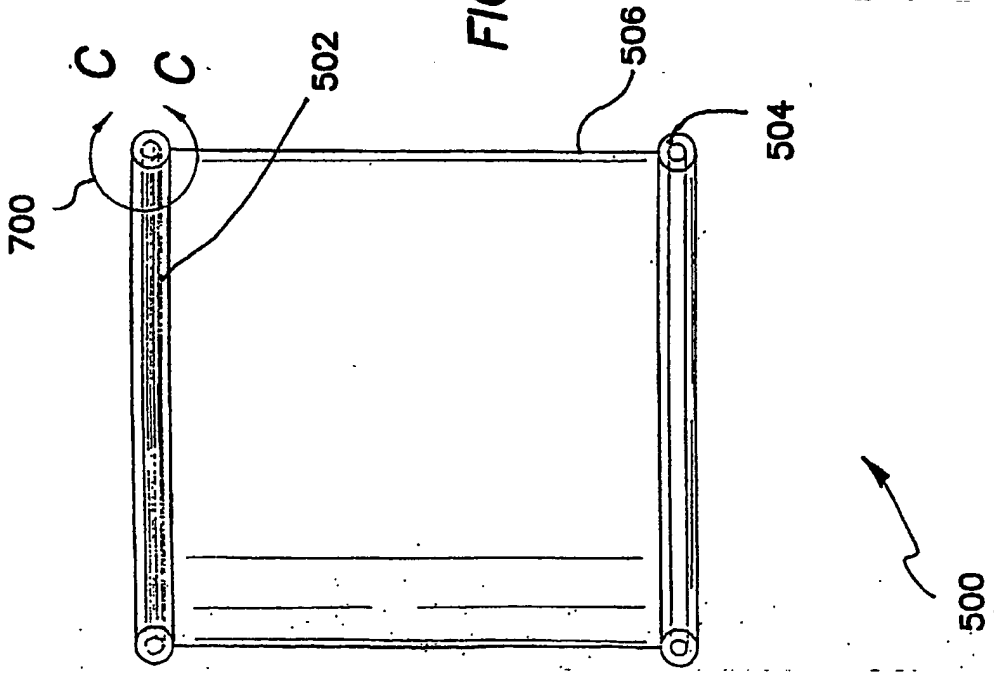


FIG. 5



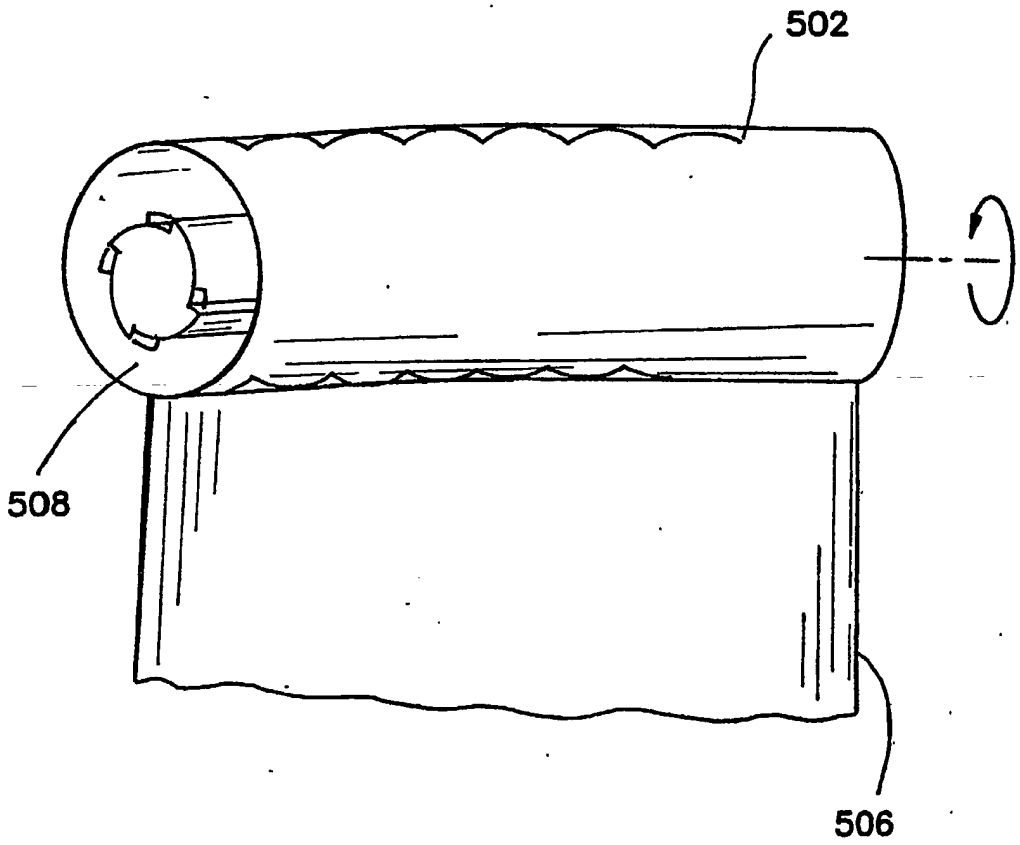


FIG. 8

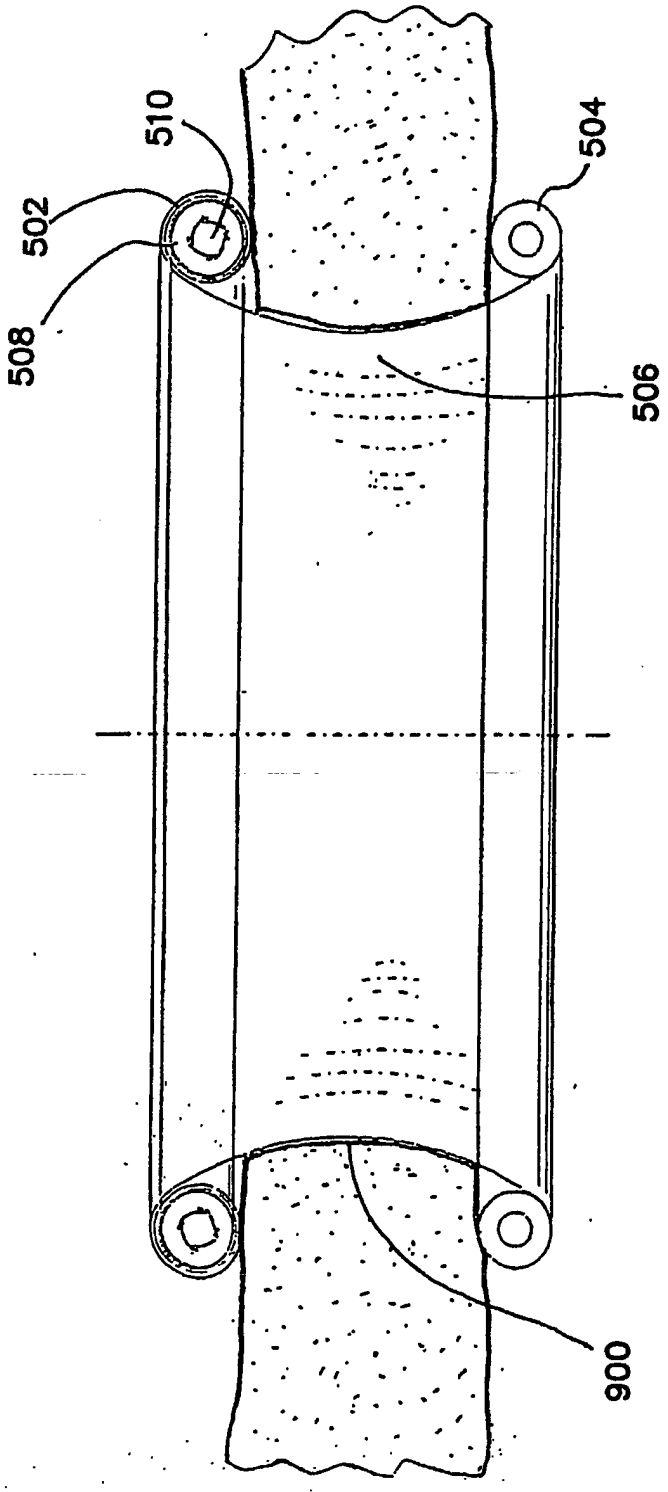


FIG. 9

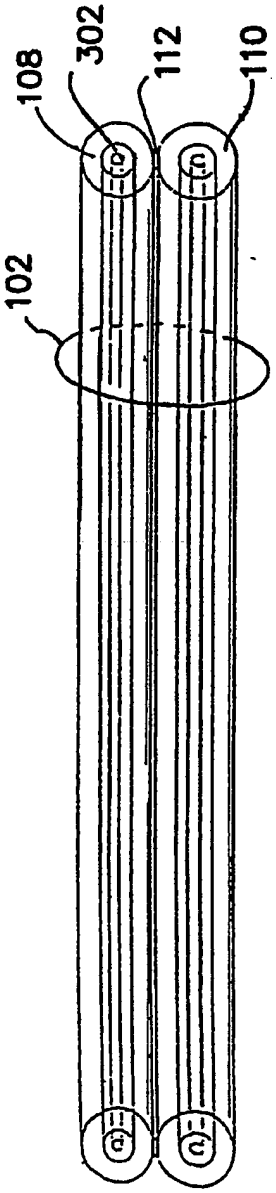


FIG. 10

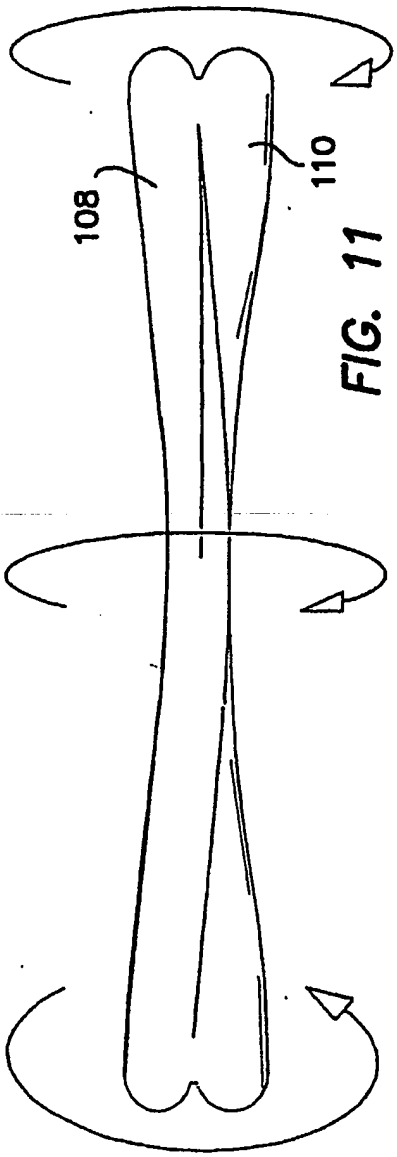


FIG. 11

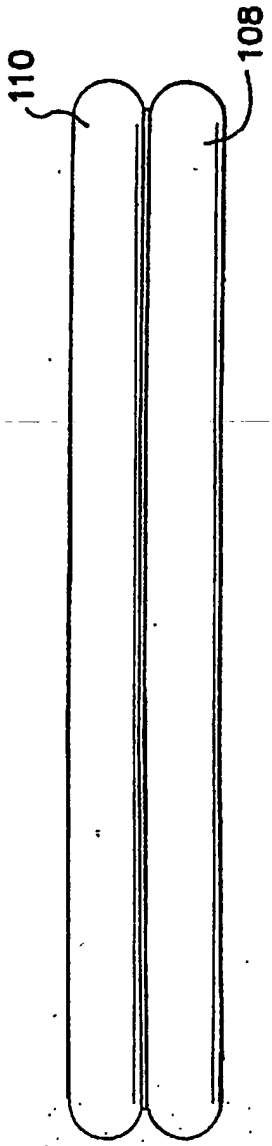


FIG. 12

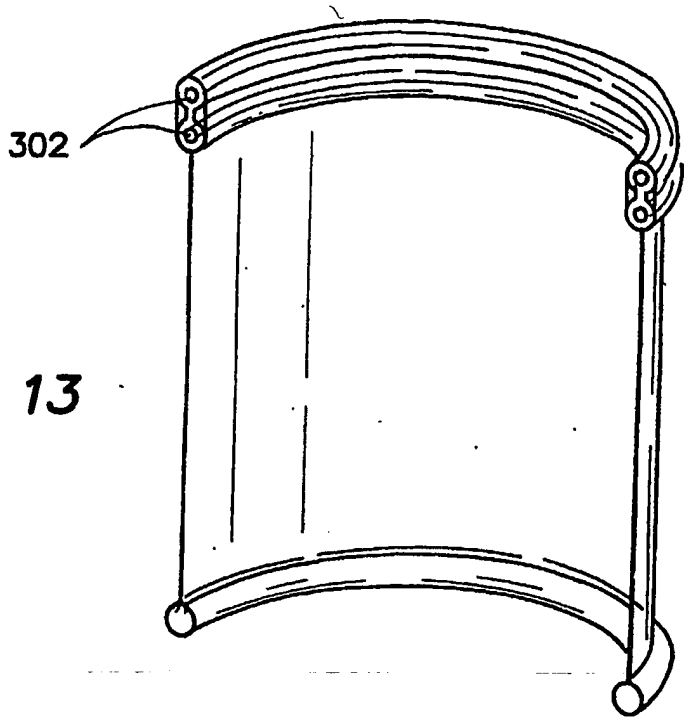


FIG. 13

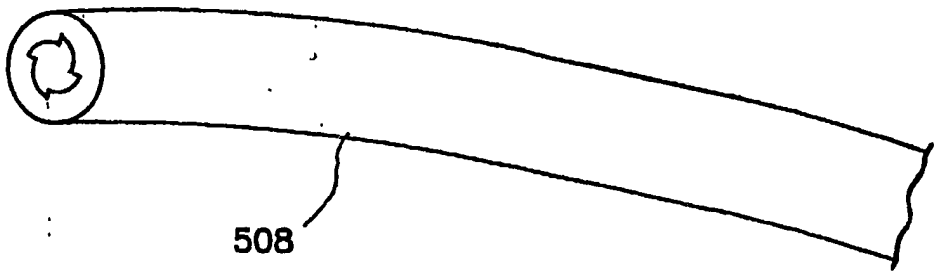


FIG. 14

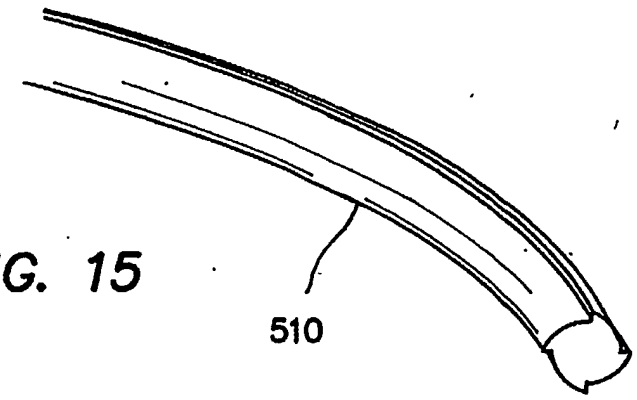


FIG. 15

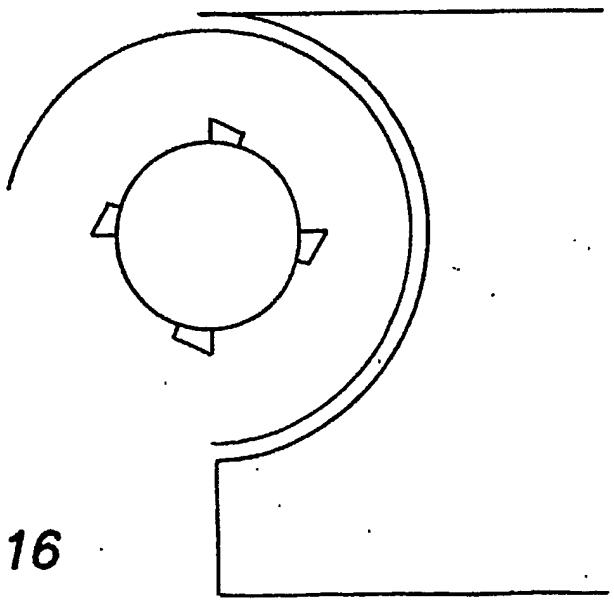


FIG. 16

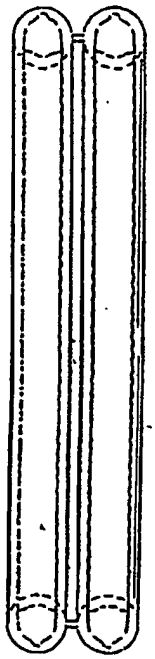


FIG. 17b

FIG. 17c

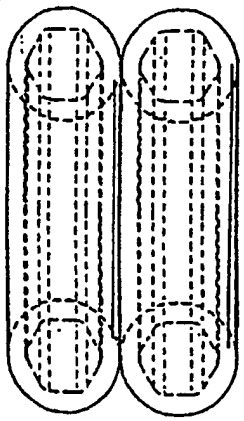


FIG. 17a

FIG. 17e

FIG. 17d

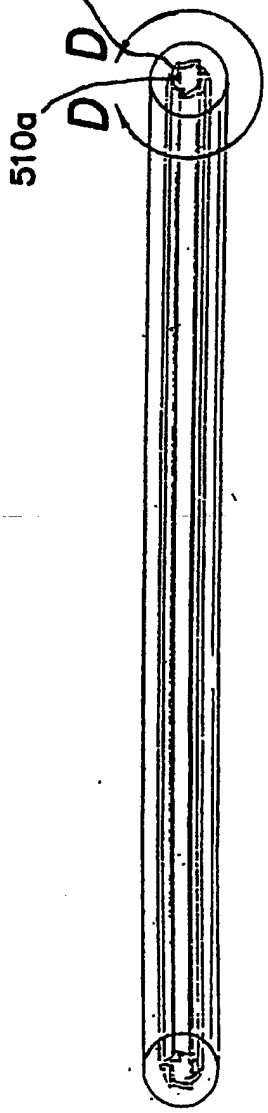
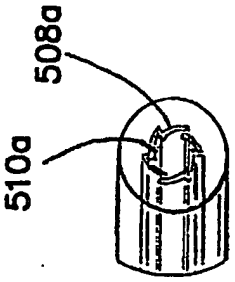


FIG. 18a



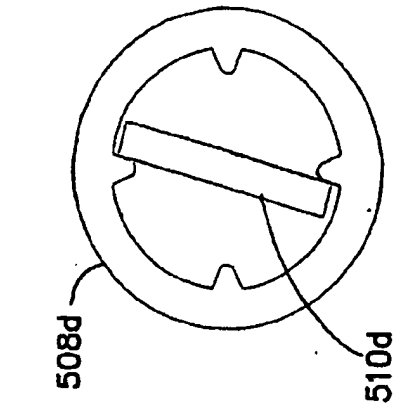


FIG. 18d

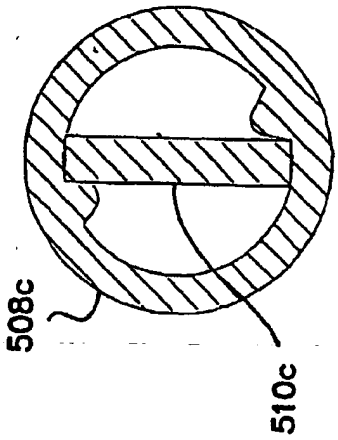


FIG. 18c

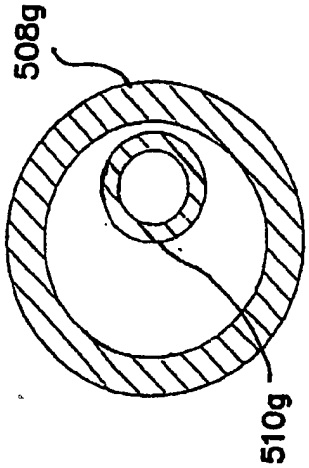


FIG. 18g

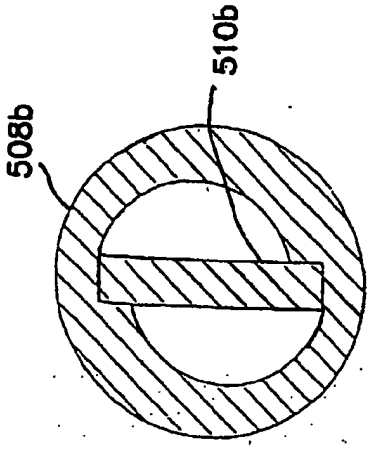


FIG. 18b

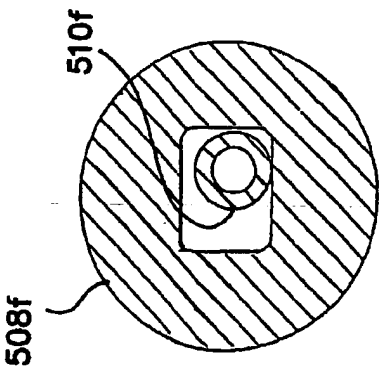


FIG. 18f

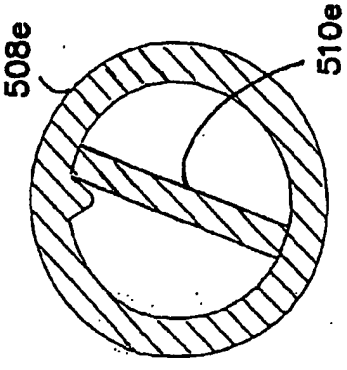


FIG. 18e

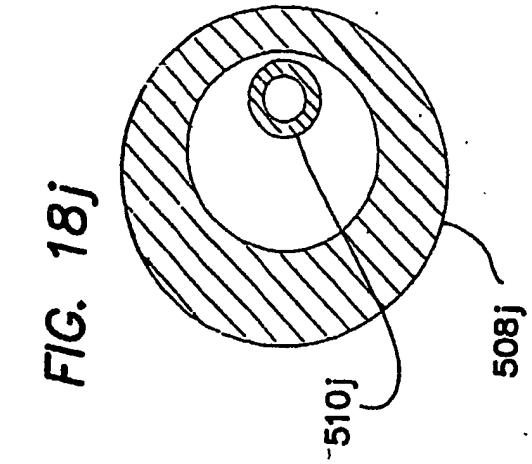


FIG. 18j

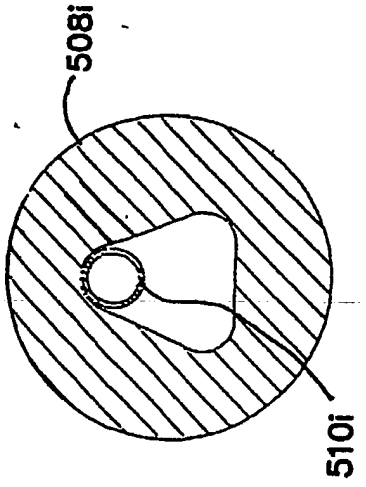


FIG. 18i

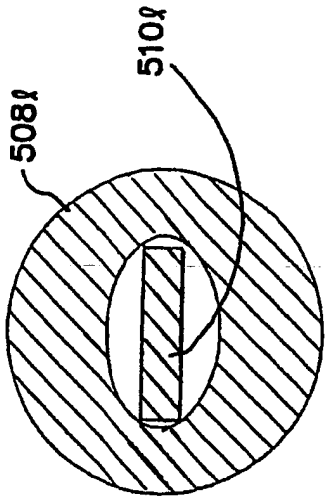


FIG. 18l

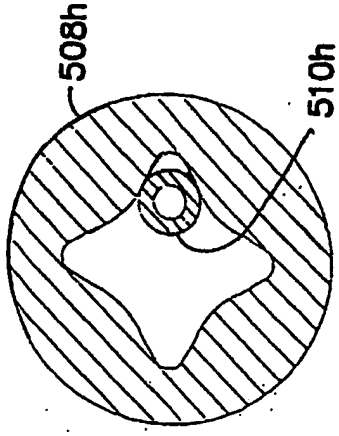


FIG. 18h

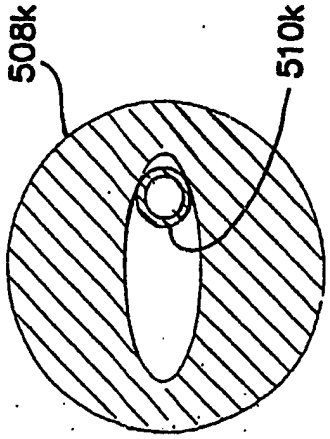


FIG. 18k

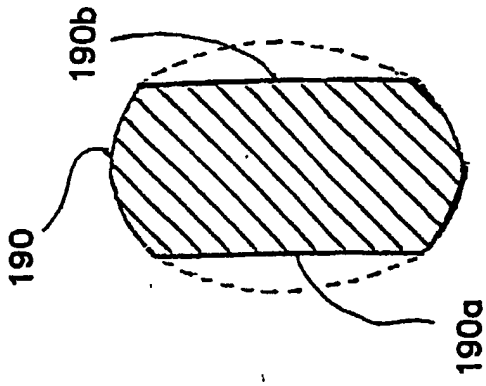


FIG. 19b

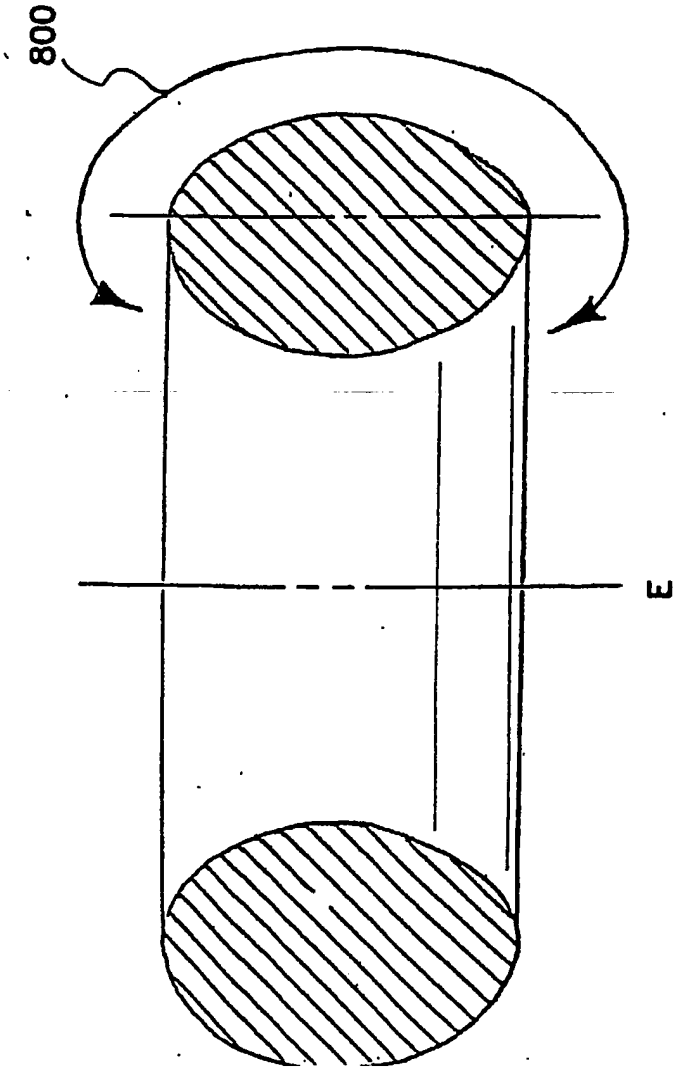


FIG. 19a

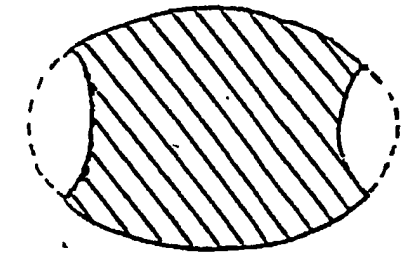


FIG. 19e

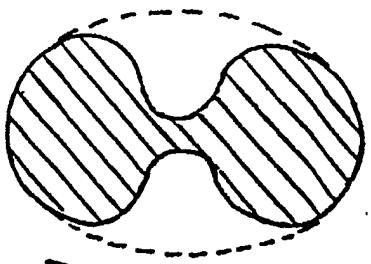


FIG. 19g

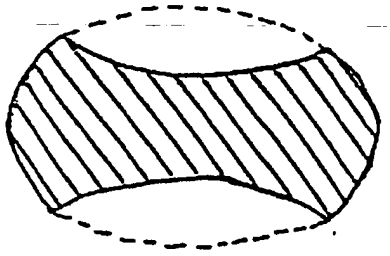


FIG. 19d

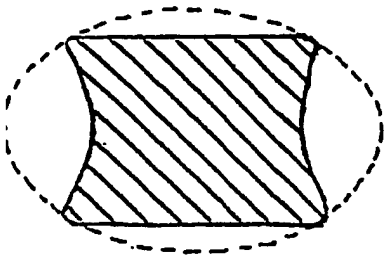


FIG. 19c

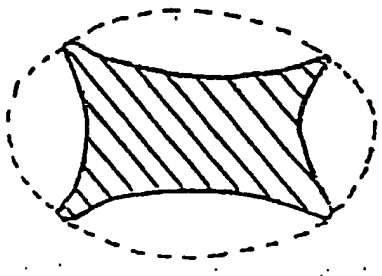


FIG. 19f

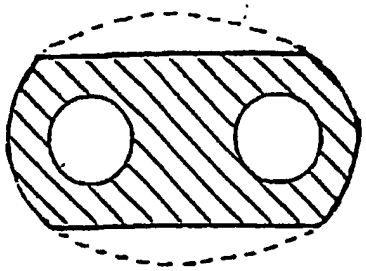


FIG. 20b

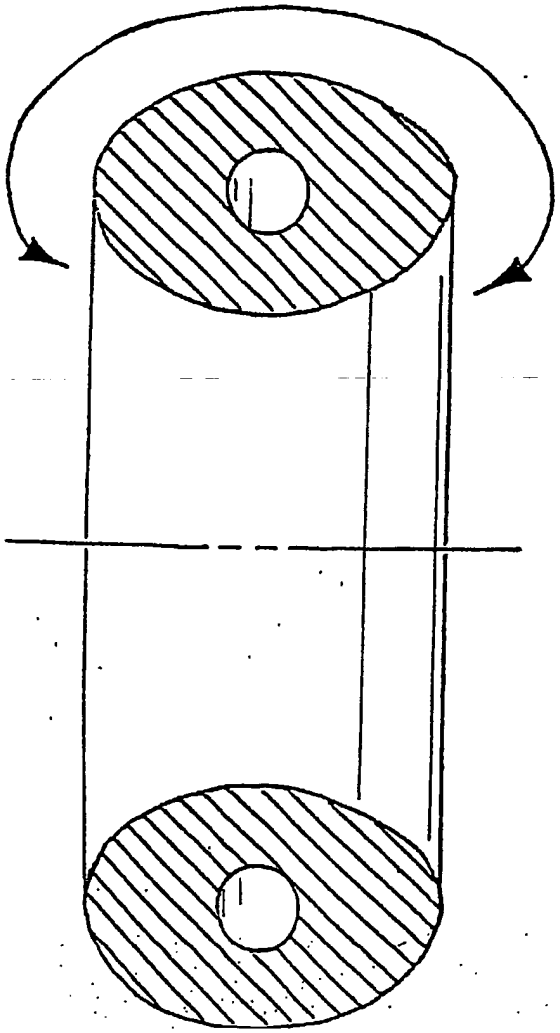


FIG. 20a

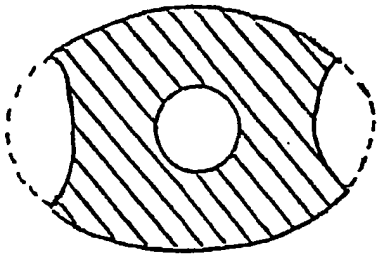


FIG. 20e

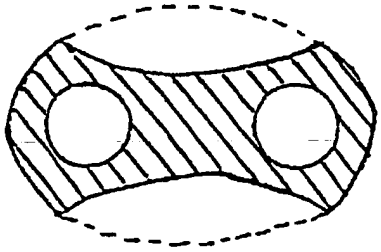


FIG. 20d

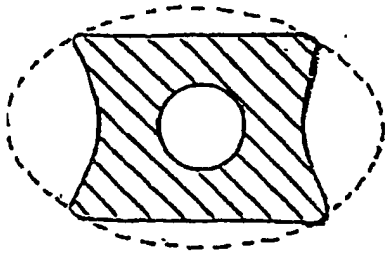


FIG. 20c

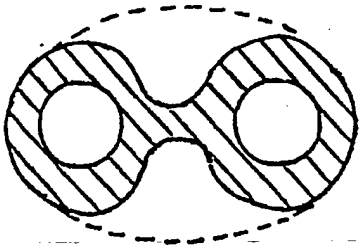


FIG. 20g

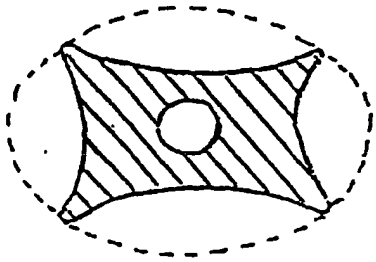


FIG. 20f

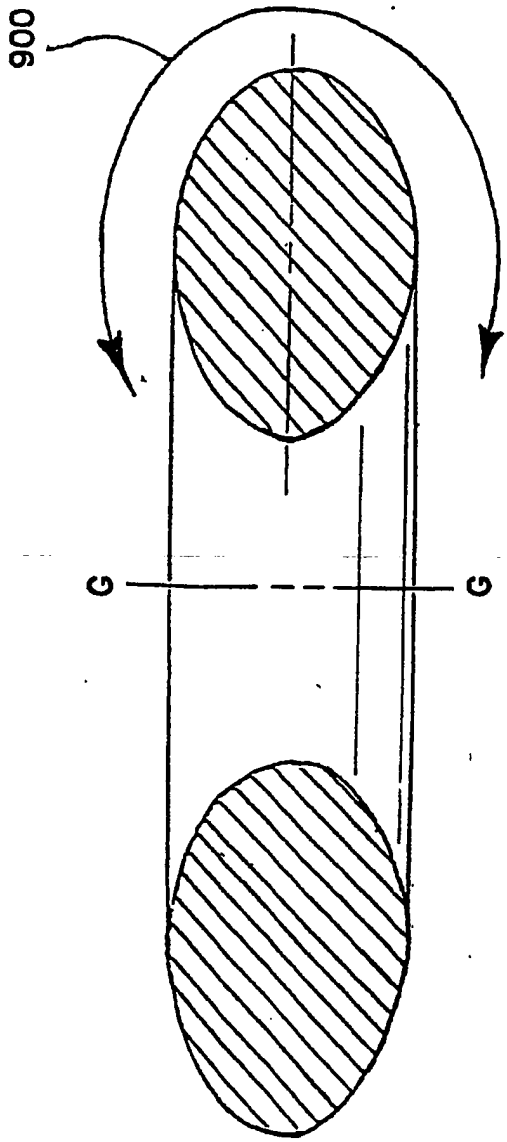


FIG. 21a

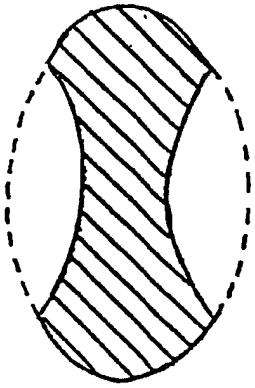


FIG. 21b

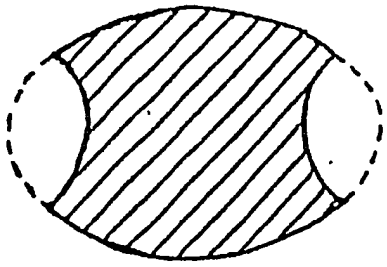


FIG. 21c

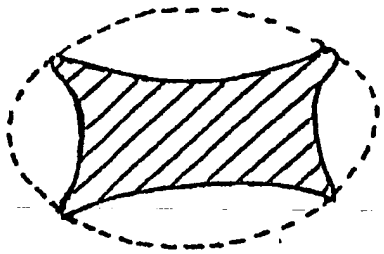


FIG. 21d

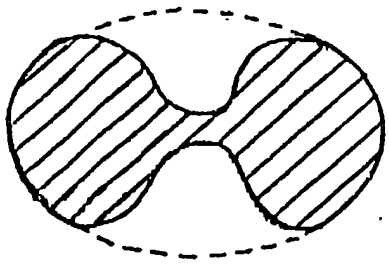


FIG. 21e

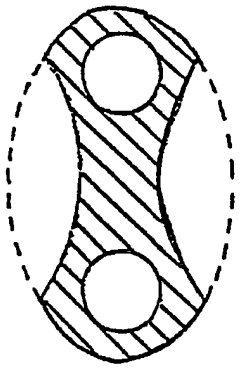


FIG. 22b

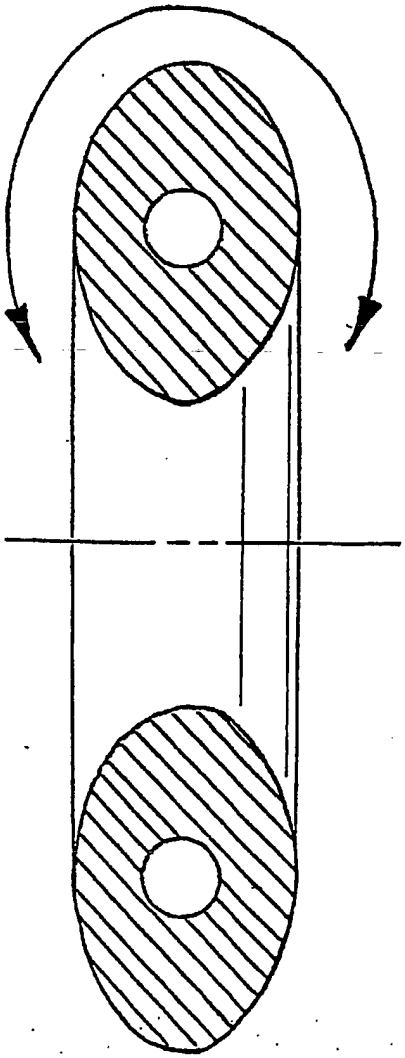


FIG. 22a

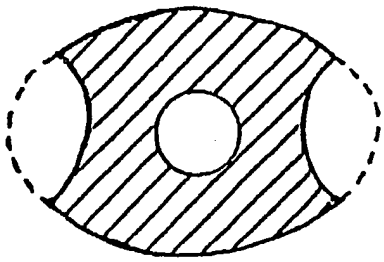


FIG. 22c

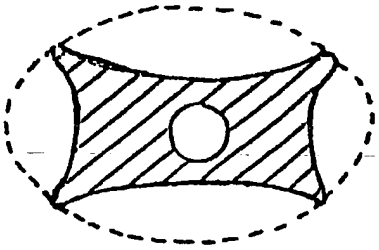


FIG. 22d

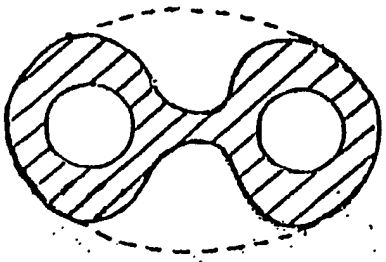


FIG. 22e

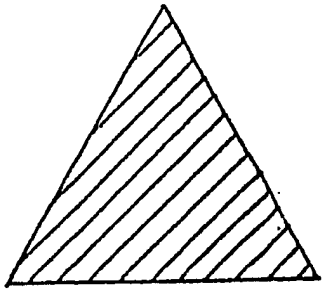
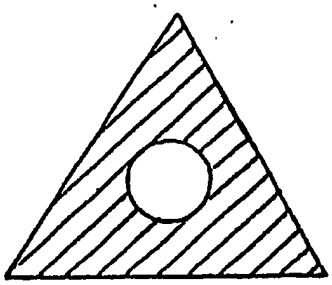


FIG. 23a

FIG. 23b



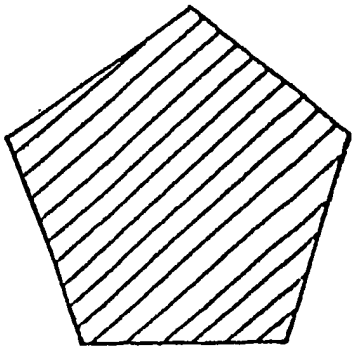
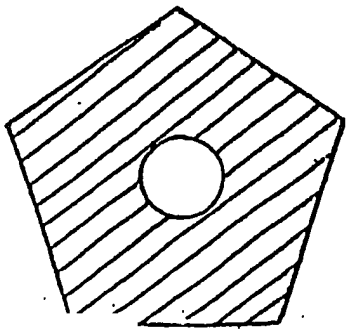


FIG. 24a

FIG. 24b



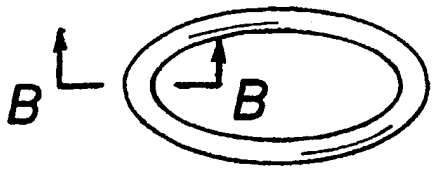


FIG. 25a

B–B

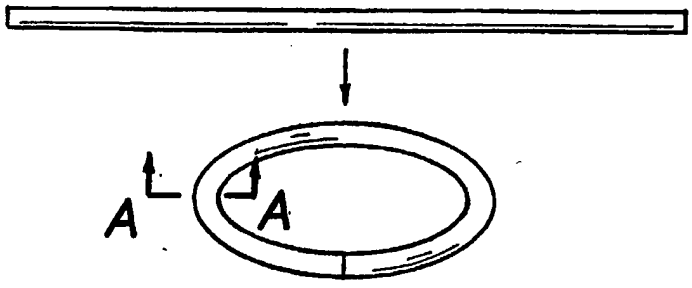


FIG. 25b

A–A

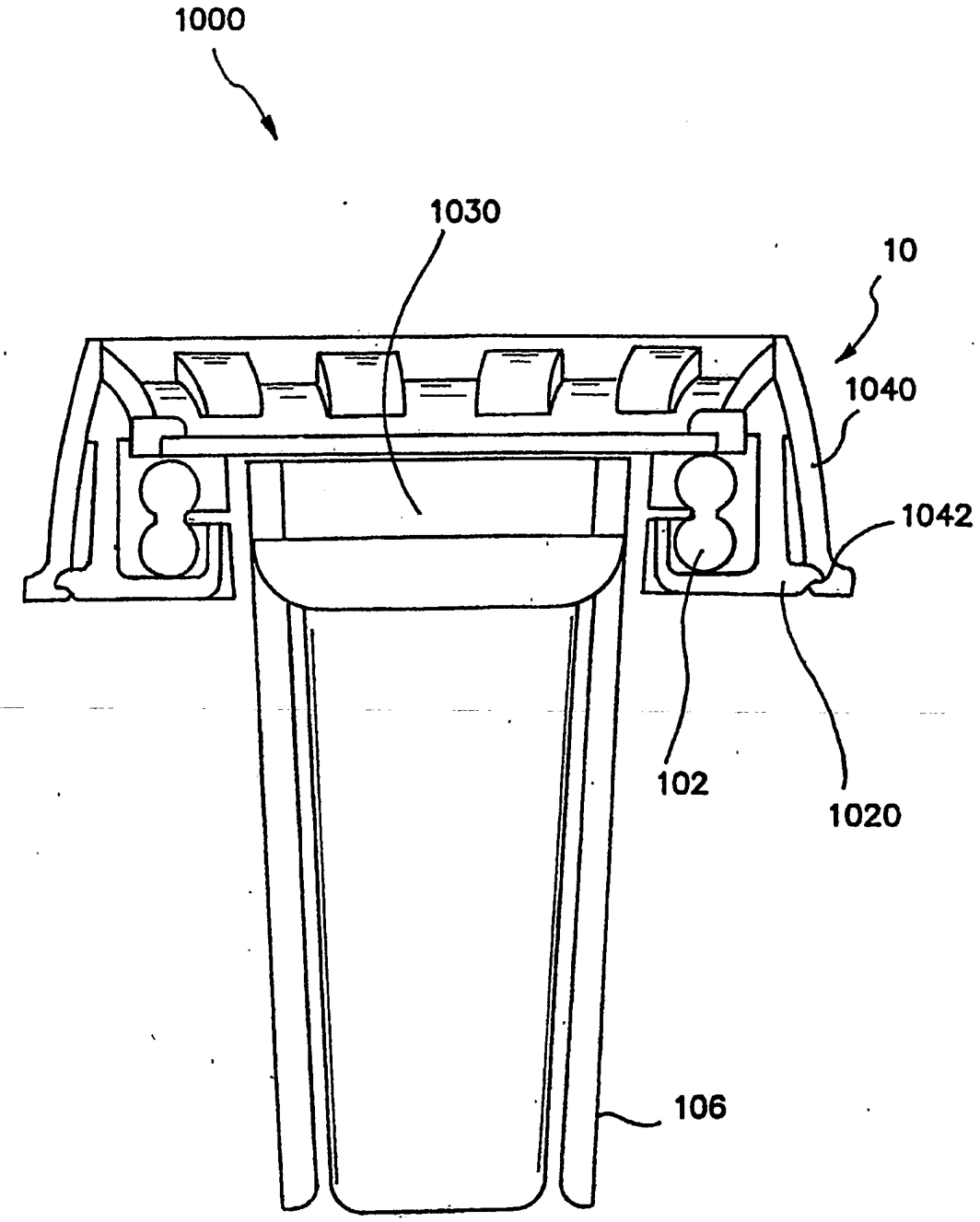


FIG. 26

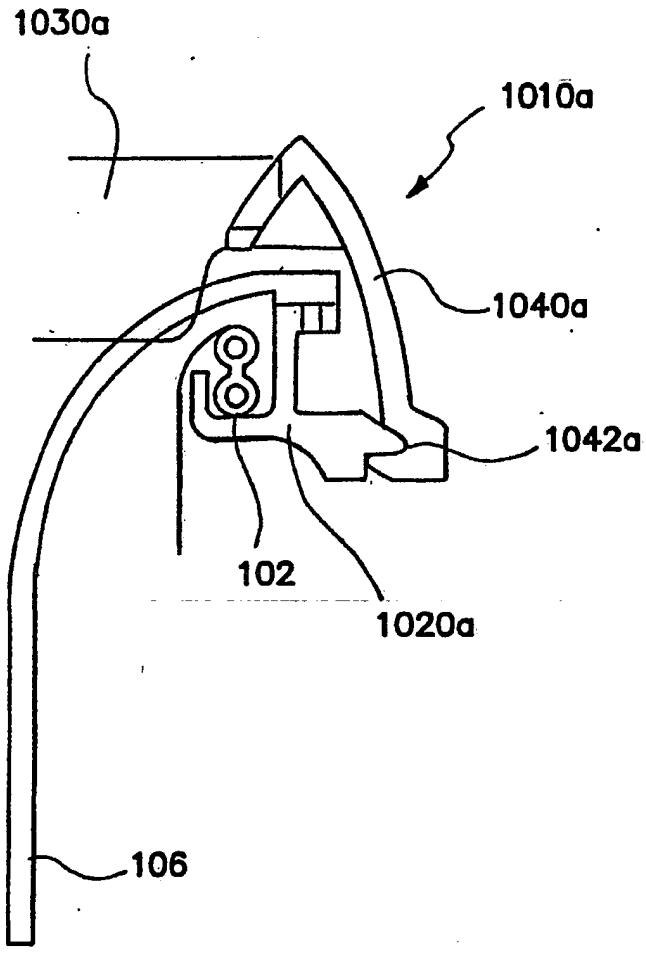


FIG. 27

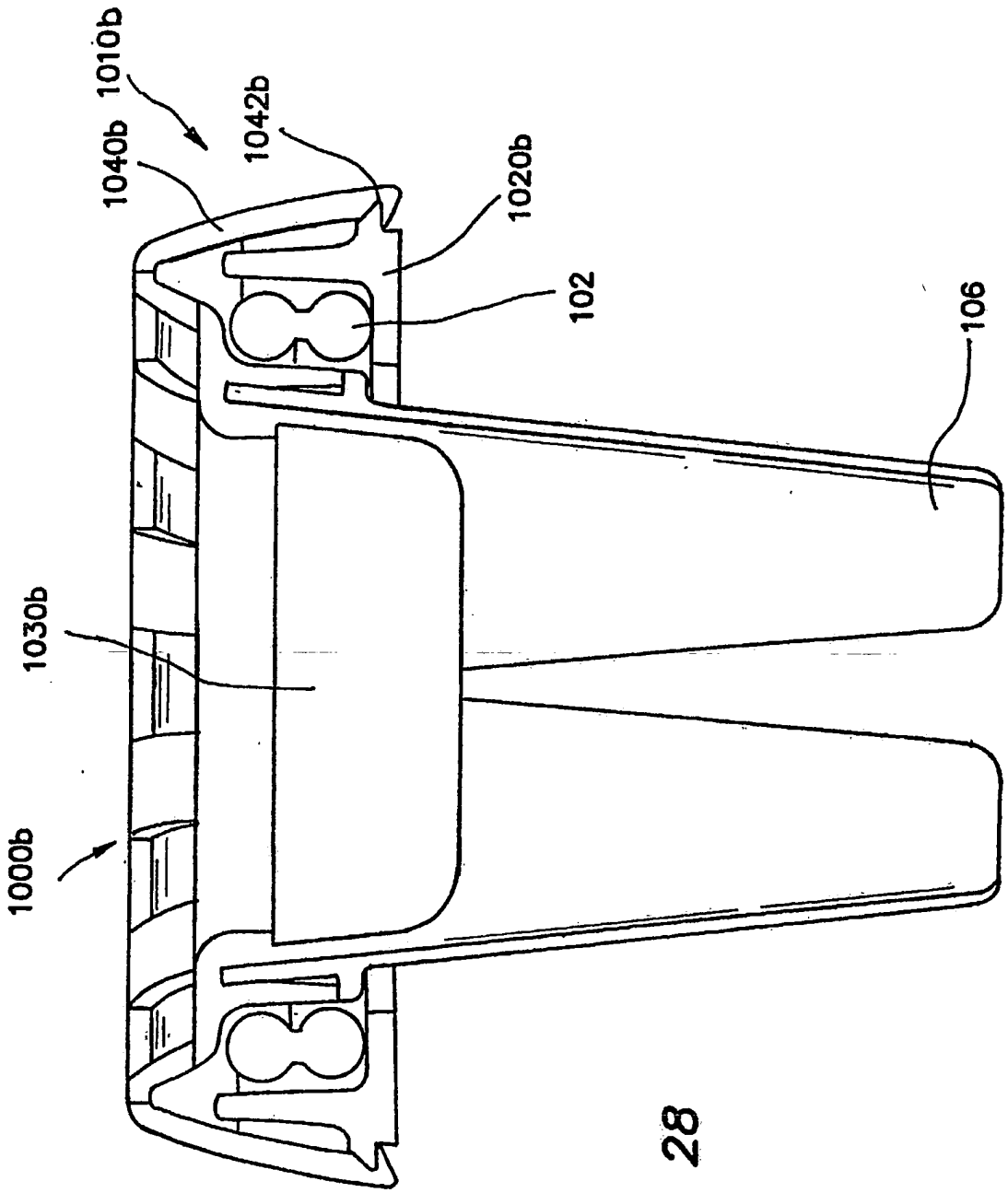


FIG. 28

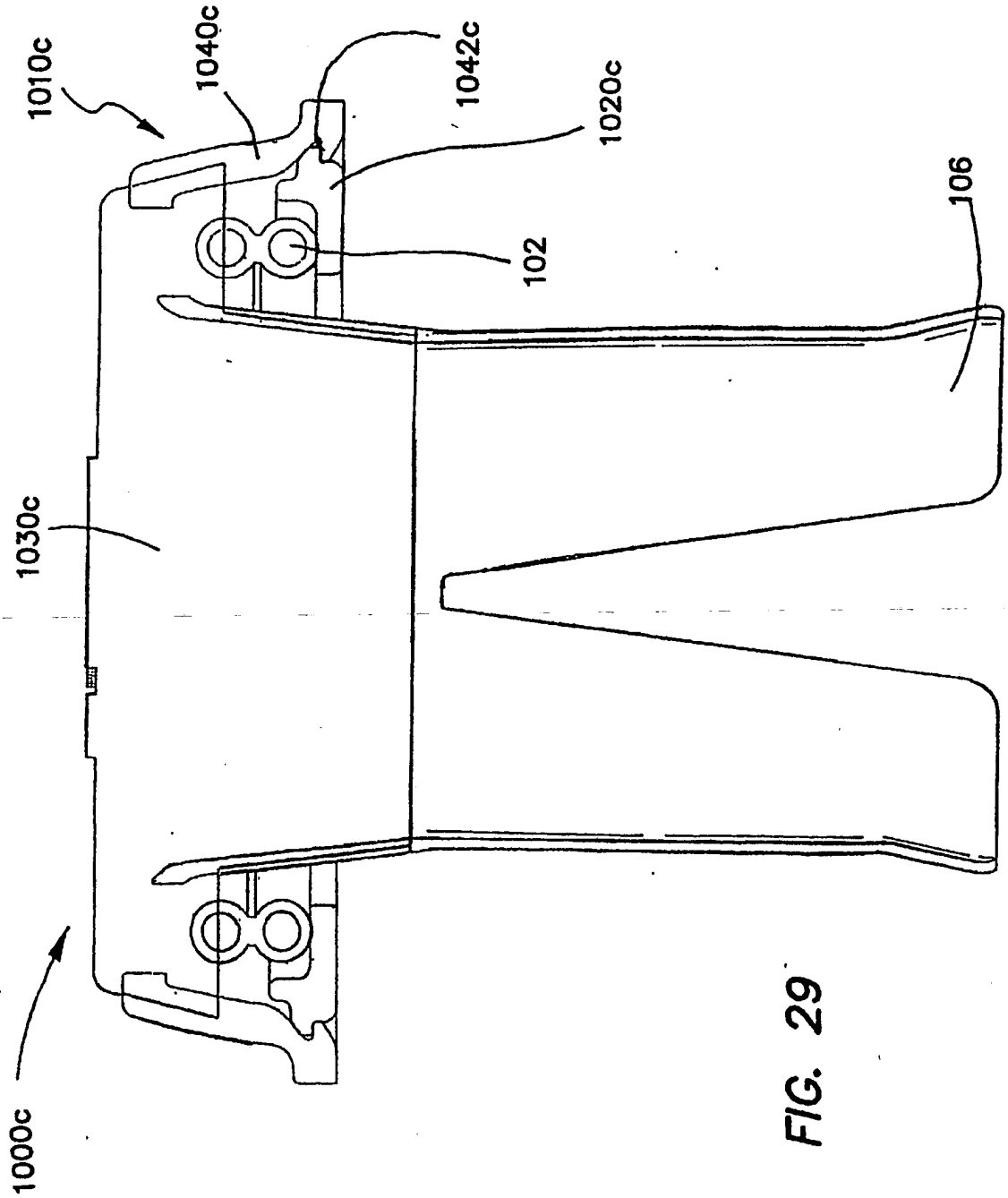


FIG. 29

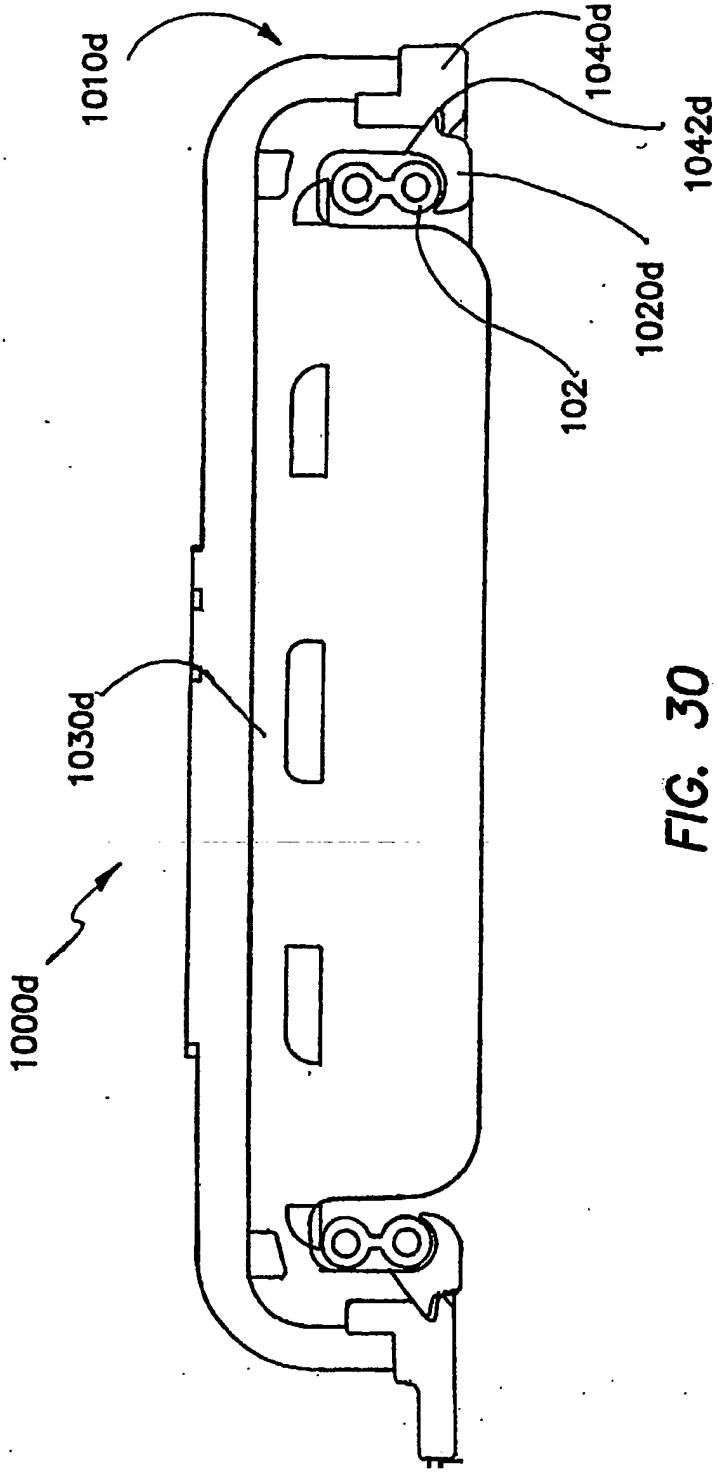


FIG. 30

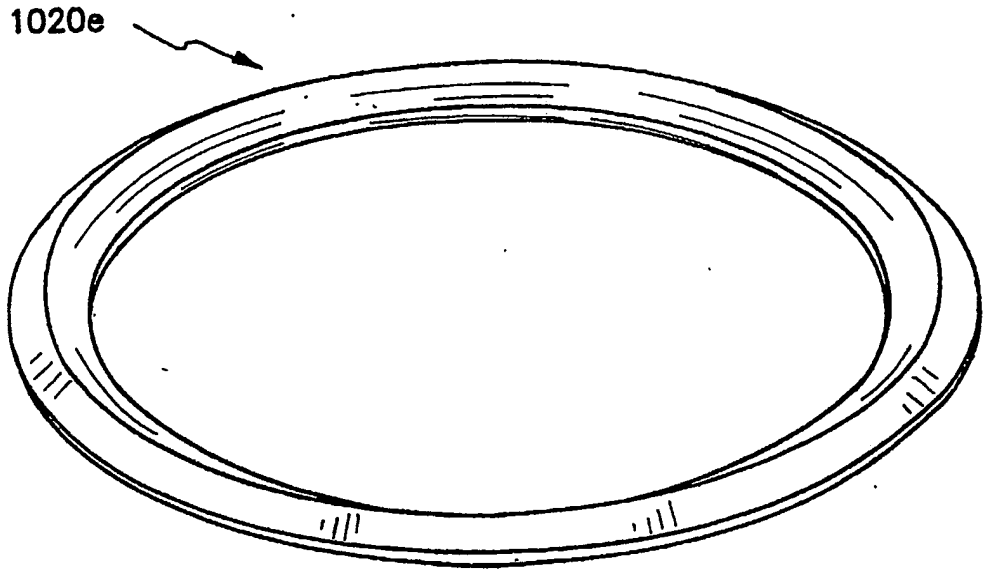


FIG. 31

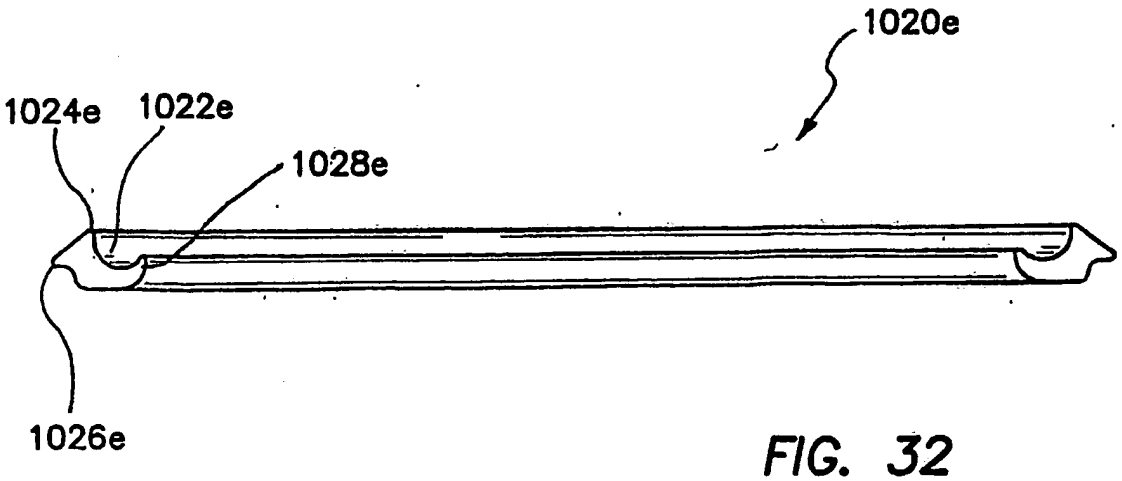


FIG. 32

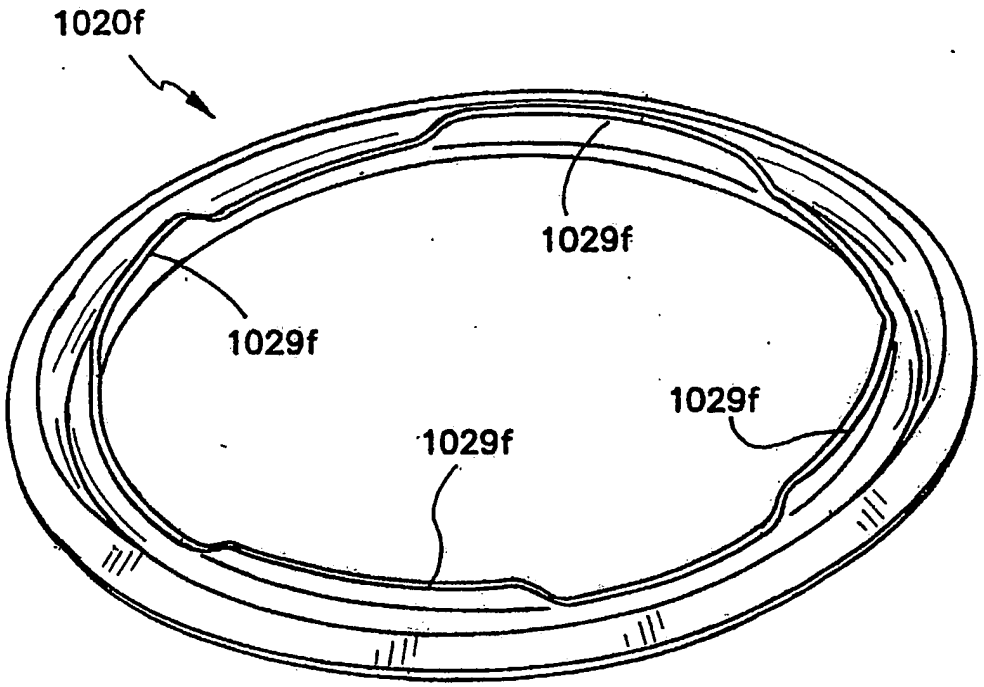

1020f
1029f
1029f
1029f
1029f

FIG. 33

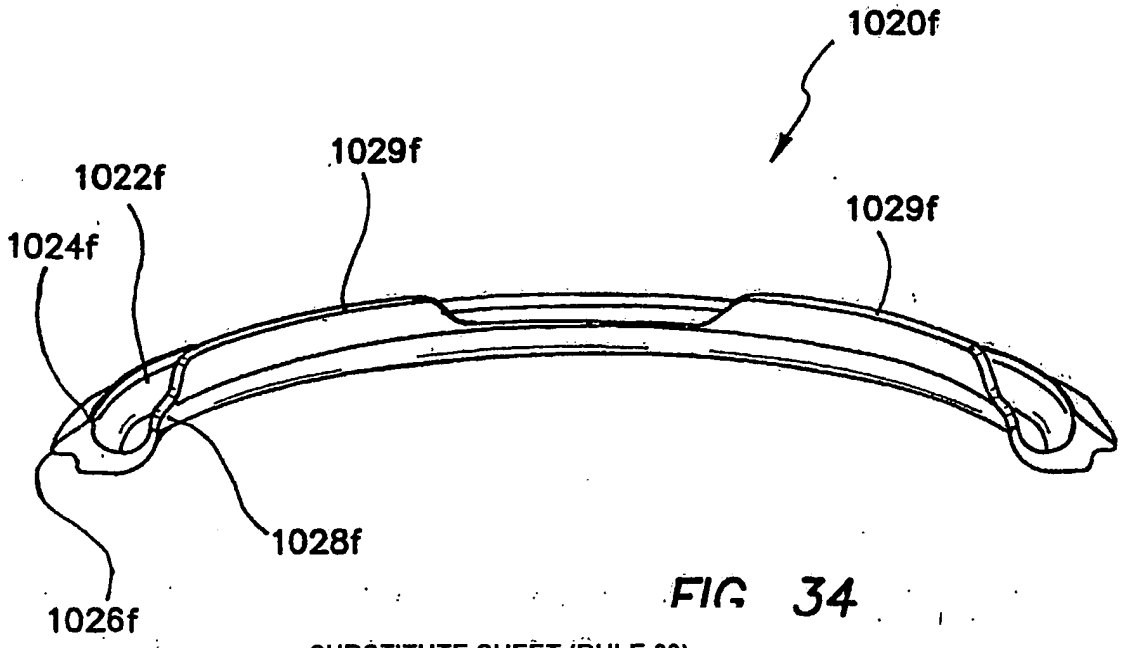

1020f
1029f
1022f
1029f
1024f
1028f
1026f

FIG. 34

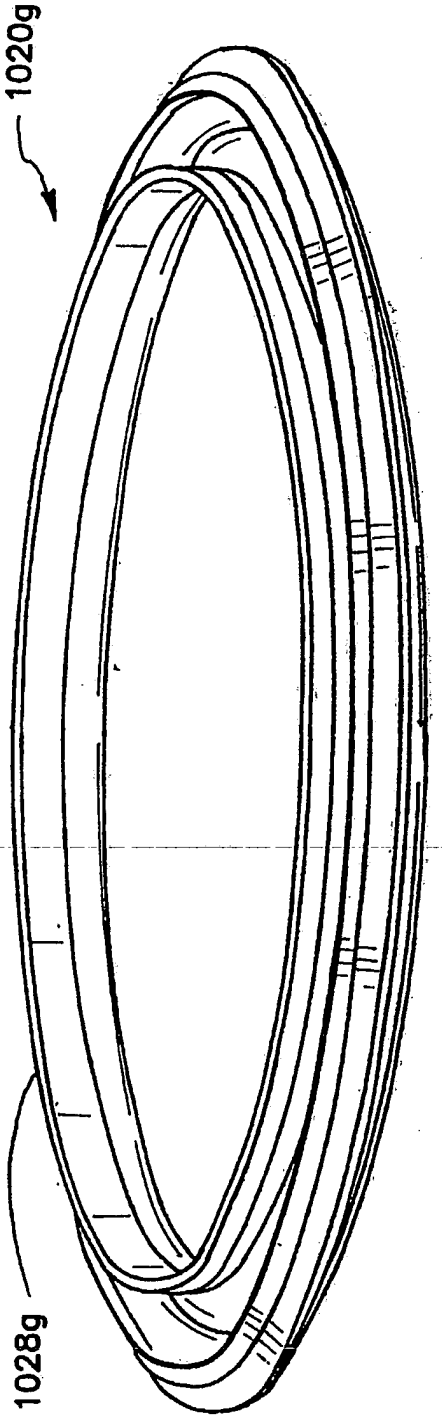


FIG. 35

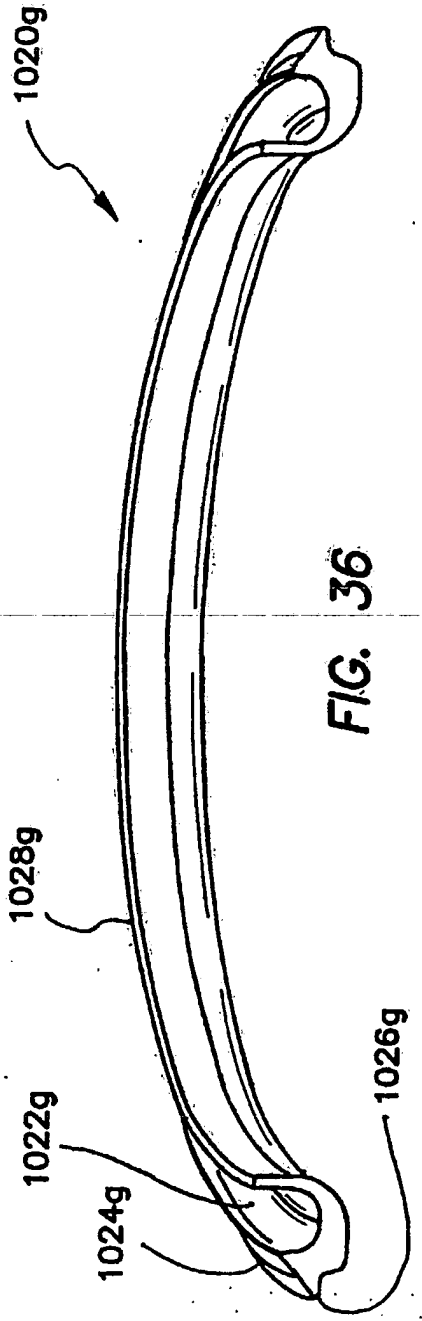


FIG. 36

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/17389

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 13/00
US CL : 128/888

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/856, 888, 889; 602/42, 43, 50, 60, 63, 75

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,524,644 A (CROOK) 11 June 1996, See the entire document	1-6, 9, 22, 24-28, 33-34

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
04 SEPTEMBER 2003	30 SEP 2003
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer MICHAEL A. BROWN
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Form PCT/ISA/210 (second sheet) (July 1998)*